

MATERIAL SAFETY DATA SHEET
TAMSULOSIN HYDROCHLORIDE

Date: 26.08.2004
Supersedes: 07.05.2003

1. SUBSTANCE/PRODUCT AND COMPANY IDENTIFICATION

TAMSULOSIN HYDROCHLORIDE

Company: Fermion Oy

Address P.O. Box 28
FIN-02101 Espoo
Finland

Tel.Int. +358-10-4291
Telefax +358-9-452 1764

2. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical nature:

TAMSULOSIN HYDROCHLORIDE 98 – 100 %

Chemical name: (R)-5-(2-[2-(2-Ethoxyphenoxy)ethylamino]
propyl)-2-methoxybenzenesulphonamide
hydrochloride

CAS: 106463-17-6

EINECS: -

Product usage: Drug substance. In treatment of benign prostatic hypertrophy.

3. HAZARD IDENTIFICATION

Harmful if swallowed. Apparently harmful by inhalation and in contact with skin.

4. FIRST AID MEASURES

4.2 Inhalation: Remove to fresh air.

4.3 Skin contact: Wash with soap and plenty of water.

4.4 Eye contact: Flush with plenty of water for at least 20 minutes. Seek medical advice.

4.5 Ingestion: Induce vomiting. Give activated charcoal. Seek medical advice.

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The usual extinguishing methods are suitable.

5.3 Special exposure hazards in a fire:

Emits toxic fumes of nitrogen and sulphur oxides and hydrogen chloride in fire.

6. ACCIDENTIAL RELEASE MEASURES

6.1 Personal precautions: Warn other people about the danger of exposure. Put on the personal safety devices.

6.3 Methods for cleaning up:

Collect the material into tight containers avoiding all exposure. Ventilate the area and clean the place.

7. HANDLING AND STORAGE

7.1 Handling: The material should be handled with care only by specially trained people avoiding all exposure and contamination. Pregnant women should avoid handling this substance.

7.2 Storage: Store in airtight containers in a cool place protected from light.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION8.2 Exposure controls8.2.1 Occupational exposure controls:

Use only in well-ventilated areas.

8.2.1.1 Respiratory protection:

Particle filtering device (P3) or compressed air line breathing apparatus.

8.2.1.2 Hand protection: Safety gloves.

8.2.1.3 Eye protection: Face shield or goggles.

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8.2.1.4 Skin protection: Protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES9.1 General information

White or almost white powder.

9.2 Important health, safety and environmental information

9.2.1 pH-value: -

9.2.2 Boiling point: -

9.2.3 Flash point: -

9.2.4 Flammability: -

9.2.5 Explosive properties

9.2.5.1 Lower explosion point:

-

9.2.5.2 Upper explosion point:

-

9.2.6 Oxidising properties: -

9.2.7 Vapour pressure: -

9.2.8 Relative density: -

9.2.9 Solubility

9.2.9.1 Water solubility: Soluble in water.

9.2.9.2 Fat solubility (solvent-oil to be specified):

Soluble in methanol and N,N-dimethylformamide.

9.2.10 Partition coefficient: n-octanol/water:

-

9.2.11 Viscosity: -

9.2.12 Vapour density: -

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9.2.13 Evaporation rate: -

9.3 Other information: Melting point: 226 – 228 °C

10. STABILITY AND REACTIVITY

Stabile in normal conditions.

11. TOXICOLOGICAL INFORMATION11.1 Acute toxicity: LD₅₀ = 650 mg/kg (rat, oral)11.2 Irritation and corrosiveness:

May irritate skin, eyes and respiratory tract.

11.5 Empirical data on effects on humans:

Headache, gastro-intestinal disturbances. Possibly methemoglobinemia. Possibly effects on the liver. Inhibition of spermatogenesis. Abnormal spermatozoa. Infertility.

12. ECOLOGICAL INFORMATION

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13. DISPOSAL CONSIDERATIONS

The packaging and other material that has been contaminated by Tamsulosin hydrochloride should be handled as hazardous waste in accordance with local and state laws and instructions.

14. TRANSPORT INFORMATION

ADR/RID: Not restricted.

IMDG: Not restricted.

ICAO/IATA: Not restricted.

15. REGULATORY INFORMATION15.1 Information on the warning label

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15.1.1 Letter code of the warning symbol and indications of danger for the preparation:

Xn Harmful

15.1.3 R-phrase(s):

R22 Harmful if swallowed.

15.1.4 S-phrase(s):

S22 Do not breathe dust.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

16. OTHER INFORMATION16.1 List of the relevant R phrases:

Harmful if swallowed.

16.5 Sources of key data used:Martindale: The Extra Pharmacopoeia, 31st Edition,
The Pharmaceutical Press. London 1996; 952.

Registry of Toxic Effects of Chemical Substances.

16.6 Information which has been added, deleted or revised:

The information above is based on available knowledge, literature and experience and cannot be considered as complete. For further information, please contact:

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