

# Medicines & Healthcare products Regulatory Agency

British Pharmacopoeia

**Quality standards** 

# SAFETY DATA SHEET

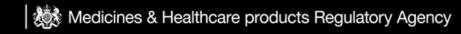
This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 31-Oct-2023

Revision Number 2

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

1.1. Product identifier			
Product Code(s)	CAT 825		
Product Name	Alfuzosin hydrochloride Assay Standard		
Form	Not applicable		
	nber is given for this substance because it is under the threshold in REACH Article istration requirements according to REACH Title II		
EC No (EU Index No)	620-512-3		
CAS No.	81403-68-1		
Chemical name	Alfuzosin hydrochloride		
Pure substance/mixture	Substance		
Formula	nula C19 H28 CI N5 O4		
Molecular weight	425.91		
1.2. Relevant identified uses of the	substance or mixture and uses advised against		
Recommended use	Laboratory use		
Uses advised against	No information available		
1.3. Details of the supplier of the sa	ifety data sheet		
Supplier			
British Pharmacopoeia Commission MHRA 10 South Colonnade Canary Wharf London E14 4PU United Kingdom			
Tel : +44 (0)20 3080 6561 eMail: bpcrs@mhra.gov.uk			





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### CAT 825 - Alfuzosin hydrochloride Assay Standard

For further information, please contact

E-mail address bpcrs@mhra.gov.uk

#### 1.4. Emergency telephone number

**Emergency Telephone** 

+44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

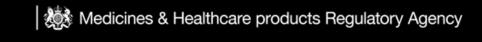
Emergency Telephone - §45 - (EC)1272/2008		
Europe	112	
Austria	No information available	
Bulgaria		
Croatia		
Cyprus		
Czech Republic		
Denmark		
France		
Hungary		
Ireland		
Italy		
Lithuania		
Luxembourg		
Netherlands		
Norway		
Portugal		
Romania		
Slovakia		
Slovenia		
Spain		
Sweden		
Switzerland		

# **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] Acute toxicity - Oral

Category 4 - (H302)





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#### 2.2. Label elements

Contains Alfuzosin hydrochloride



Warning

Hazard statements H302 - Harmful if swallowed

#### Precautionary Statements - EU (§28, 1272/2008)

P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell
P330 - Rinse mouth
P501 - Dispose of contents/ container to an approved waste disposal plant

#### 2.3. Other hazards

No information available.

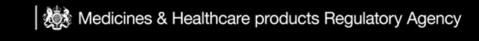
This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

This product does not contain any known or suspected endocrine disruptors.

Chemical name	EU - REACH (1907/2006) - Article 59(1)	EU - REACH (1907/2006) - Endocrine
	- Candidate List of Substances of Very	Disruptor Assessment List of
	High Concern (SVHC) for Authorisation	Substances
Alfuzosin hydrochloride	-	-

# SECTION 3: Composition/information on ingredients

#### 3.1 Substances





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		number	Index No)	to Regulation (EC) No. 1272/2008 [CLP]	concentration limit (SCL)	(long-term)
Alfuzosin hydrochloride 81403-68-1	90 - 100%	-	620-512-3	Acute Tox. 4 (H302)		

#### Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate No information available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

## SECTION 4: First aid measures

#### 4.1. Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a doctor.
Ingestion	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a doctor.

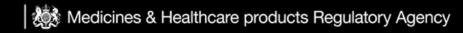
4.2. Most important symptoms and effects, both acute and delayed

Symptoms No information available.

#### 4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors Treat symptomatically.

## SECTION 5: Firefighting measures





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#### 5.1. Extinguishing media

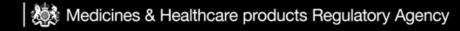
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.	
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.	
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.	
5.2. Special hazards arising from the substance or mixture		
Specific hazards arising from the chemical	No information available.	
5.3. Advice for firefighters		

**Special protective equipment and precautions for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

# **SECTION 6: Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation.	
For emergency responders	Use personal protection recommended in Section 8.	
6.2. Environmental precautions		
Environmental precautions	See Section 12 for additional Ecological Information.	
6.3. Methods and material for containment and cleaning up		
Methods for containment	Prevent further leakage or spillage if safe to do so.	
Methods for cleaning up	Take up mechanically, placing in appropriate containers for disposal.	
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.	
6.4. Reference to other sections		





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**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **SECTION 7: Handling and storage**

7.1.	Precautions	for safe	handling

Advice on safe handling Ensure adequate ventilation.

**General hygiene considerations** Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage ConditionsPlease refer to the manufacturer's certificate for specific storage and transport temperature<br/>conditions. Store only in the original receptacle unless other advice is given on the CoA.<br/>Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach<br/>of children.

#### 7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

## SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

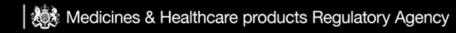
Exposure Limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

#### **Biological occupational exposure limits**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level (DNEL)No information available.Predicted No Effect ConcentrationNo information available.





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#### (PNEC)

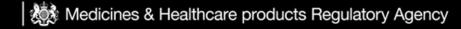
8.2. Exposure controls

Personal protective equipment	
Eye/face protection	Avoid contact with eyes. Wear safety glasses with side shields (or goggles).
Hand protection	The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear protective butyl rubber gloves.
Skin and body protection	Wear suitable protective clothing.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.
Environmental exposure controls	Do not allow into any sewer, on the ground or into any body of water.

# SECTION 9: Physical and chemical properties

9.1. Information on basic physical a	nd chemical properties	
Physical state	Solid	
Appearance	Solid	
Colour	off-white	
Odour	No information available.	
Odour threshold	No information available	
Property_	Values	
Melting point / freezing point	226 - 229 °C	
Initial boiling point and boiling rangeNo data available		
Flammability	No data available	
Flammability Limit in Air		
Upper flammability or explosive	No data available	
limits		
Lower flammability or explosive	No data available	

Remarks • Method None known None known None known None known





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None known

No information available

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limits Flash point No data available Autoignition temperature No data available **Decomposition temperature** pН No data available No data available pH (as aqueous solution) **Kinematic viscosity** No data available **Dynamic viscosity** Water solubility Solubility(ies) **Partition coefficient** Vapour pressure **Relative density Bulk density** Liquid Density Relative vapour density **Particle characteristics** Particle Size **Particle Size Distribution** 9.2. Other information

No data available Slightly soluble slightly soluble, Methanol No data available No information available No information available

425.91

Molecular formula C19 H28 CI N5 O4 9.2.1. Information with regards to physical hazard classes

Not applicable

9.2.2. Other safety characteristics No information available

## SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Molecular weight

Reactivity

No information available.

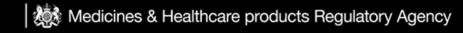
#### 10.2. Chemical stability

Stability

Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None. Sensitivity to static discharge None.





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10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

## SECTION 11: Toxicological information

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

#### Information on likely routes of exposure

#### **Product Information**

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).
Symptoms related to the physi	cal chemical and toxicological characteristics

#### Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

No information available.

#### Numerical measures of toxicity

Acute toxicity





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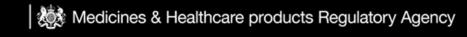
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Delayed and immediate effects as well as chronic effects from short and long-term exposure					
Skin corrosion/irritation	Based on available data, the classification criteria are not met.				
Serious eye damage/eye irritation	No information available.				
Respiratory or skin sensitisation	No information available.				
Germ cell mutagenicity	No information available.				
Carcinogenicity	No information available.				
Reproductive toxicity	No information available.				
STOT - single exposure	No information available.				
STOT - repeated exposure	No information available.				
Aspiration hazard	No information available.				
11.2. Information on other hazards					
11.2.1. Endocrine disrupting properties					
Endocrine disrupting properties	No information available.				
11.2.2. Other information					
Other adverse effects	No information available.				





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## SECTION 12: Ecological information

#### 12.1. Toxicity

Ecotoxicity

The environmental impact of this product has not been fully investigated.

#### 12.2. Persistence and degradability

Persistence and degradability No information available.

#### 12.3. Bioaccumulative potential

Bioaccumulation No information available.

#### 12.4. Mobility in soil

Mobility in soil No information available.

#### 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** This substance is not considered to be persistent, bioaccumulating nor toxic (PBT). This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

Chemical name	PBT and vPvB assessment	
Alfuzosin hydrochloride	The substance is not PBT / vPvB	

### 12.6. Endocrine disrupting properties

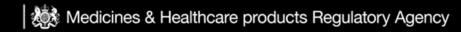
Endocrine disrupting properties No information available.

#### 12.7. Other adverse effects

No information available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods





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Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

# **SECTION 14: Transport information**

#### <u>IATA</u>

<ul> <li>14.1 UN number or ID number</li> <li>14.2 UN proper shipping name</li> <li>14.3 Transport hazard class(es)</li> <li>14.4 Packing group</li> <li>14.5 Environmental hazards</li> <li>14.6 Special precautions for user Special Provisions</li> </ul>	Not regulated Not regulated Not regulated Not applicable None
IMDG14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Marine pollutant14.6Special precautions for user Special Provisions14.7Maritime transport in bulk according to IMO instruments	Not regulated Not regulated Not regulated Not regulated Not applicable None No information available No information available
RID14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Environmental hazards14.6Special precautions for user Special Provisions	Not regulated Not regulated Not regulated Not regulated Not applicable None
ADR 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group 14.5 Environmental hazards	Not regulated Not regulated Not regulated Not regulated Not applicable





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 14.6 Special precautions for user
 None

## SECTION 15: Regulatory information

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

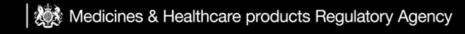
Water hazard class (WGK) slightly hazardous to water (WGK 1)

Poland

SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650) . Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194, item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

**European Union** 

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents





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at work.

#### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

# DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

**Persistent Organic Pollutants** Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

#### International Inventories TSCA

Complies under research and development exemption or is regulated by a different government agency. DSL/NDSL Contact supplier for inventory compliance status Contact supplier for inventory compliance status **EINECS/ELINCS** Contact supplier for inventory compliance status Contact supplier for inventory compliance status

Legend:

ENCS **IECSC** 

KECL PICCS

AIIC

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances **ENCS** - Japan Existing and New Chemical Substances IECSC - China Inventory of Existing Chemical Substances **KECL** - Korean Existing and Evaluated Chemical Substances **PICCS** - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances





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15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment is not required for this substance

## **SECTION 16: Other information**

Key or legend to abbreviations and acronyms used in the safety data sheet

#### Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed

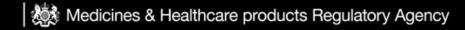
#### Legend

SVHC: Substances of Very High Concern for Authorisation:

#### Legend Section 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Classification procedure			
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used		
Acute oral toxicity	Calculation method		
Acute dermal toxicity	Calculation method		
Acute inhalation toxicity - gas	Calculation method		
Acute inhalation toxicity - Vapour	Calculation method		
Acute inhalation toxicity - dust/mist	Calculation method		
Skin corrosion/irritation	Calculation method		
Serious eye damage/eye irritation	Calculation method		
Respiratory sensitisation	Calculation method		
Skin sensitisation	Calculation method		
Mutagenicity	Calculation method		
Carcinogenicity	Calculation method		
Reproductive toxicity	Calculation method		
STOT - single exposure	Calculation method		
STOT - repeated exposure	Calculation method		
Acute aquatic toxicity	Calculation method		
Chronic aquatic toxicity	Calculation method		
Aspiration hazard	Calculation method		
Ozone	Calculation method		





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Key literature references and sources for data used to compile the SDS Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme Organisation for Economic Co-operation and Development Screening Information Data Set World Health Organization

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 Disclaimer

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be heldresponsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise. End of Safety Data Sheet