

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

#### 1.1. Product identifier

Product form	: Substance
Substance name	: Atazanavir sulfate
Product code	: 201700371
Synonyms	: Atazanavir sulfate, hydrates, isomers and impurities where applicable

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

##### 1.2.1. Relevant identified uses

Main use category	: The product is intended for research, analysis and scientific education.
Use of the substance/mixture	: For professional use only
Function or use category	: Laboratory chemicals

##### 1.2.2. Uses advised against

Restrictions on use	: Do not use : Ingestion, Inhalation, Dermal
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#### 1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare  
EDQM, Council of Europe 7, Allée Kastner, CS30026  
F- 67081 Strasbourg  
France  
T +33(0)388412035 - F +33(0)388412771  
[sds@edqm.eu](mailto:sds@edqm.eu) - [www.edqm.eu](http://www.edqm.eu)

#### 1.4. Emergency telephone number

Emergency number	: +33(0)390215608
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### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Serious eye damage/eye irritation, Category 1	H318
Specific target organ toxicity – Repeated exposure, Category 1	H372
Full text of H- and EUH-statements: see section 16	

##### Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



Signal word (CLP)	: Danger
Hazard statements (CLP)	: H318 - Causes serious eye damage. H372 - Causes damage to organs (Liver, heart) through prolonged or repeated exposure.
Precautionary statements (CLP)	: P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P264 - Wash hands, forearms and face thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove

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contact lenses, if present and easy to do. Continue rinsing.

P310 - Immediately call a POISON CENTER or doctor.

P314 - Get medical advice/attention if you feel unwell.

P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

Hazard pictograms (CLP) :



GHS08



GHS05

### 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Atazanavir sulfate	-	≤ 100	Eye Dam. 1, H318 STOT RE 1, H372

Full text of H- and EUH-statements: see section 16

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general	: Immediately flush the contact area with plenty of water.
First-aid measures after inhalation	: Move to fresh air. Allow affected person to breathe fresh air. Immediate medical attention and special treatment, if necessary.
First-aid measures after skin contact	: Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty of water and detergent. Flush with lukewarm water for 15 minutes. Get medical advice if skin irritation persists.
First-aid measures after eye contact	: Rinse with water while holding the eyes wide open. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation persists, consult an eye specialist.
First-aid measures after ingestion	: Rinse mouth. Do not induce vomiting. Specific medical surveillance. Prolonged medical observation may be indicated.

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

Symptoms/effects	: Causes burns. Delayed adverse effects possible.
Symptoms/effects after inhalation	: Insufficient data available. May cause shortness of breath, tightness of the chest, a sore throat and cough.
Symptoms/effects after skin contact	: Insufficient data available. Redness, pain.
Symptoms/effects after eye contact	: Insufficient data available. Redness, pain.
Symptoms/effects after ingestion	: Burns to the gastric/intestinal mucosa. Symptoms may include dizziness, headache, nausea and loss of coordination.

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

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active substance. Pharmaceutical.

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### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : Extinguishing blanket.

#### 5.2. Special hazards arising from the substance or mixture

Fire hazard : See Heading 2.2. Beware, risk of formation of toxic and corrosive gases.

#### 5.3. Advice for firefighters

Firefighting instructions : Use extinguishing media appropriate for surrounding fire.

### SECTION 6: Accidental release measures

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

General measures : Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.

##### 6.1.1. For non-emergency personnel

Emergency procedures : Wear suitable protective clothing, gloves and eye or face protection.

##### 6.1.2. For emergency responders

Protective equipment : See Section 8.

#### 6.2. Environmental precautions

No additional information available

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Ensure waste is collected and contained. Clean thoroughly. Material should be handled with caution. In aqueous medium : Corrosive to eyes, respiratory system and skin. Wash the non-recoverable remainder with : Sodium hypochlorite solution.

#### 6.4. Reference to other sections

No additional information available

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Additional hazards when processed : The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended. In aqueous medium : Corrosive to eyes, respiratory system and skin.

Precautions for safe handling : Material should be handled with caution. Avoid any direct contact with the product. Material should be handled in a laboratory hood whenever possible.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures.

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

Technical measures : Comply with applicable regulations.

Storage conditions : Store locked up.

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

See Heading 1.

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### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1 National occupational exposure and biological limit values

No additional information available

##### 8.1.2. Recommended monitoring procedures

No additional information available

##### 8.1.3. Air contaminants formed

No additional information available

##### 8.1.4. DNEL and PNEC

No additional information available

##### 8.1.5. Control banding

No additional information available

#### 8.2. Exposure controls

##### 8.2.1. Appropriate engineering controls

###### Appropriate engineering controls:

Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

##### 8.2.2. Personal protection equipment

###### 8.2.2.1. Eye and face protection

###### Eye protection:

Safety glasses. DIN EN 166

###### 8.2.2.2. Skin protection

###### Skin and body protection:

Use chemically protective clothing. DIN EN 13034

###### Hand protection:

Chemically resistant protective gloves. ISO 374-1

###### 8.2.2.3. Respiratory protection

###### Respiratory protection:

Dust production: dust mask with filter type P3. DIN EN 140 & 149. Liquid product : Aerosol mask. Wear breathing apparatus if exposed to vapours/dusts/aerosols

###### 8.2.2.4. Thermal hazards

No additional information available

##### 8.2.3. Environmental exposure controls

No additional information available

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Not available
Appearance	: Powder.
Odour	: Not applicable.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not applicable

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Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 1 – 10 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Stable under normal conditions.

### 10.2. Chemical stability

No additional information available

### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

None under normal use. See Section 7.

### 10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

## SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified (Inconclusive data)
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)

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LD50 oral rat	> 1600 mg/kg
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Skin corrosion/irritation	: Not classified (Lack of data)
Serious eye damage/irritation	: Causes serious eye damage.
Respiratory or skin sensitisation	: Not classified (Lack of data)

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Germ cell mutagenicity	: Not classified (Lack of data)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Not classified (Lack of data)
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Causes damage to organs (Liver, heart) through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Technical impossibility to obtain the data)

### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: Hazardous waste. Use suitable disposal containers.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

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LC50 - Fish [1]	> 89 mg/l (96Hours, Oncorhynchus mykiss (Rainbow trout))
EC50 - Crustacea [1]	> 5.4 mg/l (48Hours, Daphnia magna (Water flea))
EC50 72h - Algae [1]	> 4.1 mg/l (72 Hours, Pseudokirchneriella subcapitata)
NOEC chronic fish	> 8.6 mg/l (32days, Pimephales promelas)
NOEC chronic crustacea	5.1 mg/l (21days, Daphnia magna (Water flea))

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

No additional information available

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional legislation (waste)	: Dispose in a safe manner in accordance with local/national regulations.
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## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

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ADR	IMDG	IATA
<b>14.1. UN number or ID number</b>		
Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>		
Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>		
Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>		
Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>		
Not applicable	Not applicable	Not applicable
No supplementary information available		

### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not applicable

#### Air transport

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

##### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

##### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

##### PIC Regulation (Prior Informed Consent)

Not applicable.

##### POP Regulation (Persistent Organic Pollutants)

Not applicable.

##### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

##### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

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### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

### Full text of H- and EUH-statements:

Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H318	Causes serious eye damage.
H372	Causes damage to organs through prolonged or repeated exposure.
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.