

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

#### 1.1. Product identifier

Product form : Mixture  
Product name : Saxagliptin for system suitability  
Product code : 202200297

#### 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

#### 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

### SECTION 2: Hazards identification

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

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

Respiratory sensitisation, Category 1	H334
Skin sensitisation, Category 1	H317
Reproductive toxicity, Category 2	H361
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) :



GHS08

Signal word (CLP) :

Danger

Contains :

(1aS,4S,6aR,7aS)-4-(3-hydroxyadamantan-1-yl)hexahydro-1H-cyclopropa[4,5]pyrrolo[1,2-a]pyrazine-3,6-dione; Saxagliptin hydrate

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H361 - Suspected of damaging fertility or the unborn child.  
H372 - Causes damage to organs through prolonged or repeated exposure.

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Precautionary statements (CLP) : P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
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.  
P272 - Contaminated work clothing should not be allowed out of the workplace.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
P284 - Wear respiratory protection.  
P302+P352 - IF ON SKIN: Wash with plenty of water.  
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P314 - Get medical advice/attention if you feel unwell.  
P321 - Specific treatment (see supplemental first aid instruction on this label).  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor.  
P362+P364 - Take off contaminated clothing and wash it before reuse.  
P405 - Store locked up.  
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

Hazardous ingredients : (1aS,4S,6aR,7aS)-4-(3-hydroxyadamantan-1-yl)hexahydro-1H-cyclopropa[4,5]pyrrolo[1,2-a]pyrazine-3,6-dione; Saxagliptin hydrate

### 2.3. Other hazards

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Saxagliptin hydrate	-	99,8	Resp. Sens. 1, H334 Skin Sens. 1A, H317 Repr. 2, H361 STOT RE 1, H372
(1aS,4S,6aR,7aS)-4-(3-hydroxyadamantan-1-yl)hexahydro-1H-cyclopropa[4,5]pyrrolo[1,2-a]pyrazine-3,6-dione	-	0,2	Resp. Sens. 1, H334 Skin Sens. 1A, H317 Repr. 2, H361 STOT RE 1, H372

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

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### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures after inhalation	: Move to fresh air. Allow affected person to breathe fresh air.
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.
First-aid measures after eye contact	: Rinse with water while holding the eyes wide open.
First-aid measures after ingestion	: Rinse mouth. Prolonged medical observation may be indicated.

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

Symptoms/effects	: Delayed adverse effects possible.
Symptoms/effects after inhalation	: Insufficient data available.
Symptoms/effects after skin contact	: Insufficient data available.
Symptoms/effects after eye contact	: Insufficient data available.

#### 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.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media	: Extinguishing blanket.
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#### 5.2. Special hazards arising from the substance or mixture

Fire hazard	: See Heading 2.2.
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#### 5.3. Advice for firefighters

Firefighting instructions	: Use extinguishing media appropriate for surrounding fire.
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### 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.
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##### 6.1.1. For non-emergency personnel

Emergency procedures	: Wear suitable protective clothing, gloves and eye or face protection.
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##### 6.1.2. For emergency responders

No additional information available

#### 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. Wash the non-recoverable remainder with : Sodium hypochlorite solution.
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#### 6.4. Reference to other sections

No additional information available

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### 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.
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.

### 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 an 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

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### 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
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
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	: Not available
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.

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### 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 (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)

#### Saxagliptin hydrate

LD50 oral rat	> 2000 mg/kg
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Suspected of damaging fertility or the unborn child.
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Causes damage to organs through prolonged or repeated exposure.

#### (1aS,4S,6aR,7aS)-4-(3-hydroxyadamantan-1-yl)hexahydro-1H-cyclopropa[4,5]pyrrolo[1,2-a]pyrazine-3,6-dione

STOT-repeated exposure	Causes damage to organs (endocrine system, immune system, skin) through prolonged or repeated exposure (if swallowed).
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#### Saxagliptin hydrate

STOT-repeated exposure	Causes damage to organs (endocrine system, immune system, skin) through prolonged or repeated exposure (if swallowed).
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Aspiration hazard	: Not classified (Technical impossibility to obtain the data)
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### 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 (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)
Not rapidly degradable	

### 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

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### 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.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

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

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### 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)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

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

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

###### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

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

Not applicable.

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

Not applicable.

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

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

###### 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)

###### 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

#### Indication of changes:

Classification of the substance or mixture.

Full text of H- and EUH-statements:	
H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361	Suspected of damaging fertility or the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
Repr. 2	Reproductive toxicity, Category 2
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Resp. Sens. 1	H334	Calculation method
Skin Sens. 1	H317	Calculation method



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### Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Repr. 2	H361	Calculation method
STOT RE 1	H372	Calculation method

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.