

# Sitagliptin containing impurity A

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Issue date: 13/03/2025 Version: 1.0

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

#### 1.1. Product identifier

Product form : Substance  
Substance name : Sitagliptin containing impurity A  
Chemical name : Sitagliptin phosphate monohydrate  
CAS-No. : 654671-77-9  
Product code : 202500195

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

##### Relevant identified uses

Use of the substance/mixture : Scientific research and development  
Technical testing and analysis  
For professional use only  
Function or use category : Laboratory chemicals

##### Uses advised against

Restrictions on use : Not for food, drug or home use

#### 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]

Serious eye damage/eye irritation, Category 2 H319  
Specific target organ toxicity – Repeated exposure, Category 2 H373  
Full text of H- and EUH-statements: see section 16

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

Causes serious eye irritation. May cause damage to organs through prolonged or repeated exposure.

#### 2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

GHS08

Signal word (CLP) : Warning  
Hazard statements (CLP) : H319 - Causes serious eye irritation.  
H373 - May cause damage to organs 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.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing

# Sitagliptin containing impurity A

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

protection.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

P337+P313 - If eye irritation persists: Get medical advice/attention.

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

### 2.3. Other hazards

Other information

: Active substance (in pharmaceutical products).  
Warning - substance not yet tested completely.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

| Name                              | Product identifier   | %     | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|-----------------------------------|----------------------|-------|---|
| Sitagliptin phosphate monohydrate | CAS-No.: 654671-77-9 | ≤ 100 | Eye Irrit. 2, H319<br>STOT RE 2, H373                           |

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

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

|                                       |  |
|---------------------------------------|--|
| First-aid measures general            | : In all cases of doubt, or when symptoms persist, seek medical attention.   |
| First-aid measures after inhalation   | : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.  |
| First-aid measures after skin contact | : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.  |
| First-aid measures after eye contact  | : Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists. |
| First-aid measures after ingestion    | : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.   |

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

Symptoms/effects after eye contact : Causes serious eye irritation. Redness, pain.

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

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

|                                |   |
|--------------------------------|---|
| Suitable extinguishing media   | : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket. |
| Unsuitable extinguishing media | : Do not use a heavy water stream.  |

# Sitagliptin containing impurity A

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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

Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.

### 5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.  
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

## SECTION 6: Accidental release measures

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

General measures : Avoid contact with skin, eyes and clothing.

#### For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

#### For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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

For containment : Absorb with an inert material and place in an appropriate waste disposal container.  
Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

### 6.4. Reference to other sections

See Section 13 for disposal information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.  
Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

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

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.  
Packaging materials : Keep in original containers.

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

# Sitagliptin containing impurity A

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 8.2. Exposure controls

#### Appropriate engineering controls

##### Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

#### Personal protection equipment

##### Eye and face protection

##### Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

##### Skin protection

##### Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

##### Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

##### Respiratory protection

##### Respiratory protection:

In case of dust formation use respirator with filter: P3

## SECTION 9: Physical and chemical properties

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

|   |                         |
|---|-------------------------|
| Physical state                                  | : Solid                 |
| Colour  | : white. almost white.  |
| Appearance                                      | : Powder.               |
| Molecular mass                                  | : 523.3 g/mol           |
| Odour   | : Not available         |
| Odour threshold                                 | : Not available         |
| Melting point                                   | : ≈ 220 °C              |
| Freezing point                                  | : Not available         |
| Boiling point                                   | : Not available         |
| Flammability                                    | : Not available         |
| 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: 33.3 – 100 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

No additional information available

# Sitagliptin containing impurity A

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No additional information available

#### 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

No additional information available

#### 10.6. Hazardous decomposition products

No additional information available

### 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 (Lack of data)  
Acute toxicity (inhalation) : Not classified (Lack of data)

#### Sitagliptin phosphate monohydrate (654671-77-9)

|                                   |   |
|-----------------------------------|---|
| LD50 oral rat                     | > 3000 mg/kg  |
| Skin corrosion/irritation         | : Not classified (Based on available data, the classification criteria are not met) |
| Serious eye damage/irritation     | : Causes serious eye irritation.  |
| Respiratory or skin sensitisation | : Not classified (Based on available data, the classification criteria are not met) |
| 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             | : Not classified (Based on available data, the classification criteria are not met) |
| STOT-single exposure              | : Not classified (Lack of data)   |
| STOT-repeated exposure            | : May cause damage to organs through prolonged or repeated exposure.                |
| Aspiration hazard                 | : Not classified (Lack of data)   |

#### 11.2. Information on other hazards

No additional information available

### SECTION 12: Ecological information

#### 12.1. Toxicity

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)

#### Sitagliptin phosphate monohydrate (654671-77-9)

|                      |  |
|----------------------|--|
| LC50 - Fish [1]      | > 100 mg/l (96 Hours, Pimephales promelas) (OECD 203 method)     |
| EC50 - Crustacea [1] | 60 mg/l (48 Hours, Daphnia magna (Water flea)) (OECD 202 method) |

# Sitagliptin containing impurity A

## Safety Data Sheet

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|                        |   |
|------------------------|---|
| EC50 72h - Algae [1]   | > 39 mg/l (96 Hours, Pseudokirchneriella subcapitata (Green algae)) (OECD 201 method) |
| NOEC chronic fish      | 9.2 mg/l (33 days, Pimephales promelas) (OECD 210 method)                             |
| NOEC chronic crustacea | 9.8 mg/l (21 days, Daphnia magna (Water flea)) (OECD 211 method)                      |
| NOEC chronic algae     | 2.2 mg/l (96 Hours, Pseudokirchneriella subcapitata (Green algae)) (OECD 201 method)  |

### 12.2. Persistence and degradability

#### Sitagliptin phosphate monohydrate (654671-77-9)

|                               |                        |
|-------------------------------|------------------------|
| Persistence and degradability | Not rapidly degradable |
|-------------------------------|------------------------|

### 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

No additional information available

## 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  |                |                |

# Sitagliptin containing impurity A

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 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

#### 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

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

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

##### Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

##### 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)

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

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

|              |  |
|--------------|--|
| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2                      |
| H319         | Causes serious eye irritation.                                     |
| H373         | May cause damage to organs through prolonged or repeated exposure. |
| STOT RE 2    | Specific target organ toxicity – Repeated exposure, Category 2     |

Safety Data Sheet (SDS), EU

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