

# Ritonavir for peak identification

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Issue date: 08/01/2026 Version: 1.0

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

#### 1.1. Product identifier

Product form : Substance  
Substance name : Ritonavir for peak identification  
Chemical name : Ritonavir  
CAS-No. : 155213-67-5  
Product code : 202600004

#### 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  
Carcinogenicity, Category 2 H351  
Specific target organ toxicity – Repeated exposure, Category 2 H373  
Hazardous to the aquatic environment – Acute Hazard, H400 (M=100)  
Category 1  
Hazardous to the aquatic environment – Chronic Hazard, H410 (M=10)  
Category 1  
Full text of H- and EUH-statements: see section 16

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

Very toxic to aquatic life with long lasting effects. Suspected of causing cancer. 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) :



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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Signal word (CLP)              | : Warning                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Hazard statements (CLP)        | : H319 - Causes serious eye irritation.<br>H351 - Suspected of causing cancer.<br>H373 - May cause damage to organs (liver, pancreas) through prolonged or repeated exposure.<br>H410 - Very toxic to aquatic life with long lasting effects.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Precautionary statements (CLP) | : P201 - Obtain special instructions before use.<br>P202 - Do not handle until all safety precautions have been read and understood.<br>P260 - Do not breathe dust/fume/gas/mist/vapours/spray.<br>P264 - Wash hands, forearms and face thoroughly after handling.<br>P273 - Avoid release to the environment.<br>P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.<br>P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P314 - Get medical advice/attention if you feel unwell.<br>P337+P313 - If eye irritation persists: Get medical advice/attention.<br>P391 - Collect spillage.<br>P405 - Store locked up.<br>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).<br>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]                                                           |
|-----------|----------------------|-------|---------------------------------------------------------------------------------------------------------------------------|
| Ritonavir | CAS-No.: 155213-67-5 | ≤ 100 | Eye Irrit. 2, H319<br>Carc. 2, H351<br>STOT RE 2, H373<br>Aquatic Acute 1, H400 (M=100)<br>Aquatic Chronic 1, H410 (M=10) |

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. |

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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.

### 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

Additional hazards when processed : Do not expose pregnant or breastfeeding women.  
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.

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### 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

### 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            | : 720,9 g/mol          |
| Odour                     | : Not available        |
| Odour threshold           | : Not available        |
| Melting point             | : Not available        |
| 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: < 0,1 g/l     |

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|                                                 |                  |
|-------------------------------------------------|------------------|
| Partition coefficient n-octanol/water (Log Kow) | : > 4,5          |
| 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

## 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 (Based on available data, the classification criteria are not met)    |
| Acute toxicity (inhalation)       | : Not classified (Lack of data)                                                        |
| 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                   | : Suspected of causing cancer.                                                         |
| 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 (liver, pancreas) through prolonged or repeated exposure. |
| Aspiration hazard                 | : Not classified (Lack of data)                                                        |

### 11.2. Information on other hazards

No additional information available

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### SECTION 12: Ecological information

#### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Very toxic to aquatic life.

Hazardous to the aquatic environment, long-term (chronic) : Very toxic to aquatic life with long lasting effects.

| Ritonavir (155213-67-5) |                                                |
|-------------------------|------------------------------------------------|
| LC50 - Fish [1]         | 0,062 mg/l                                     |
| EC50 - Crustacea [1]    | 0,004 mg/l                                     |
| EC50 72h - Algae [1]    | 0,0023 mg/l                                    |
| NOEC chronic algae      | 1,59 mg/l (96 Hours, Green algae) (literature) |

#### 12.2. Persistence and degradability

| Ritonavir (155213-67-5)       |                        |
|-------------------------------|------------------------|
| Persistence and degradability | Not rapidly degradable |

#### 12.3. Bioaccumulative potential

| Ritonavir (155213-67-5)                         |       |
|-------------------------------------------------|-------|
| Partition coefficient n-octanol/water (Log Kow) | > 4,5 |

#### 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                                               |
|----------------------------------------------------|----------------------------------------------------|----------------------------------------------------|
| 14.1. UN number or ID number                       |                                                    |                                                    |
| UN 3077                                            | UN 3077                                            | UN 3077                                            |
| 14.2. UN proper shipping name                      |                                                    |                                                    |
| ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. | Environmentally hazardous substance, solid, n.o.s. |

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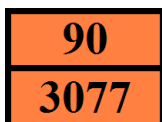
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| ADR                                                                               | IMDG                                                                                                          | IATA                                                                                |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| <b>Transport document description</b>                                             |                                                                                                               |                                                                                     |
| UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-)           | UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT                          | UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III                  |
| <b>14.3. Transport hazard class(es)</b>                                           |                                                                                                               |                                                                                     |
| 9                                                                                 | 9                                                                                                             | 9                                                                                   |
|  |                              |  |
| <b>14.4. Packing group</b>                                                        |                                                                                                               |                                                                                     |
| III                                                                               | III                                                                                                           | III                                                                                 |
| <b>14.5. Environmental hazards</b>                                                |                                                                                                               |                                                                                     |
| Dangerous for the environment: Yes                                                | Dangerous for the environment: Yes<br>Marine pollutant: Yes<br>EmS-No. (Fire): F-A<br>EmS-No. (Spillage): S-F | Dangerous for the environment: Yes                                                  |
| No supplementary information available                                            |                                                                                                               |                                                                                     |

### 14.6. Special precautions for user

#### Overland transport

|                                                                         |                           |
|-------------------------------------------------------------------------|---------------------------|
| Classification code (ADR)                                               | : M7                      |
| Special provisions (ADR)                                                | : 274, 335, 375, 601      |
| Limited quantities (ADR)                                                | : 5kg                     |
| Excepted quantities (ADR)                                               | : E1                      |
| Packing instructions (ADR)                                              | : P002, IBC08, LP02, R001 |
| Special packing provisions (ADR)                                        | : PP12, B3                |
| Mixed packing provisions (ADR)                                          | : MP10                    |
| Portable tank and bulk container instructions (ADR)                     | : T1, BK1, BK2, BK3       |
| Portable tank and bulk container special provisions (ADR)               | : TP33                    |
| Tank code (ADR)                                                         | : SGAV, LGBV              |
| Vehicle for tank carriage                                               | : AT                      |
| Transport category (ADR)                                                | : 3                       |
| Special provisions for carriage - Packages (ADR)                        | : V13                     |
| Special provisions for carriage - Bulk (ADR)                            | : VC1, VC2                |
| Special provisions for carriage - Loading, unloading and handling (ADR) | : CV13                    |
| Hazard identification number (Kemler No.)                               | : 90                      |
| Orange plates                                                           | :                         |



|                               |     |
|-------------------------------|-----|
| Tunnel restriction code (ADR) | : - |
|-------------------------------|-----|

#### Transport by sea

|                                   |                                |
|-----------------------------------|--------------------------------|
| Special provisions (IMDG)         | : 274, 335, 375, 966, 967, 969 |
| Limited quantities (IMDG)         | : 5 kg                         |
| Excepted quantities (IMDG)        | : E1                           |
| Packing instructions (IMDG)       | : LP02, P002                   |
| Special packing provisions (IMDG) | : PP12                         |
| IBC packing instructions (IMDG)   | : IBC08                        |
| IBC special provisions (IMDG)     | : B3                           |
| Tank instructions (IMDG)          | : BK1, BK2, BK3, T1            |

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Tank special provisions (IMDG) : TP33  
Stowage category (IMDG) : A  
Stowage and handling (IMDG) : SW23

### Air transport

PCA Excepted quantities (IATA) : E1  
PCA Limited quantities (IATA) : Y956  
PCA limited quantity max net quantity (IATA) : 30kgG  
PCA packing instructions (IATA) : 956  
PCA max net quantity (IATA) : 400kg  
CAO packing instructions (IATA) : 956  
CAO max net quantity (IATA) : 400kg  
Special provisions (IATA) : A97, A158, A179, A197, A215  
ERG code (IATA) : 9L

### 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 (EU 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 (EC 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:

|                   |                                                                   |
|-------------------|-------------------------------------------------------------------|
| Aquatic Acute 1   | Hazardous to the aquatic environment – Acute Hazard, Category 1   |
| Aquatic Chronic 1 | Hazardous to the aquatic environment – Chronic Hazard, Category 1 |
| Carc. 2           | Carcinogenicity, Category 2                                       |
| Eye Irrit. 2      | Serious eye damage/eye irritation, Category 2                     |
| H319              | Causes serious eye irritation.                                    |



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

|           |                                                                                      |
|-----------|--------------------------------------------------------------------------------------|
| H351      | Suspected of causing cancer.                                                         |
| H373      | May cause damage to organs (liver, pancreas) through prolonged or repeated exposure. |
| H400      | Very toxic to aquatic life.                                                          |
| H410      | Very toxic to aquatic life with long lasting effects.                                |
| STOT RE 2 | Specific target organ toxicity – Repeated exposure, Category 2                       |

Safety Data Sheet (SDS), EU

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