

# Rizatriptan benzoate

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
 Issue date: 03/04/2023 Revision date: 16/10/2025 Supersedes version of: 03/04/2023 Version: 2.0

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

#### 1.1. Product identifier

Product form	: Substance
Substance name	: Rizatriptan benzoate
Chemical name	: Rizatriptan benzoate
CAS-No.	: 145202-66-0
Product code	: 201600802

#### 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
Reproductive toxicity, Category 2	H361d
Specific target organ toxicity – single exposure, Category 1	H370
Specific target organ toxicity – Single exposure, Category 3,	H336
Narcosis	

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

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

Suspected of damaging the unborn child. Causes serious eye irritation. Causes damage to organs. May cause drowsiness or dizziness.

#### 2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

GHS08

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H319 - Causes serious eye irritation.

: H336 - May cause drowsiness or dizziness.

# Rizatriptan benzoate

## Safety Data Sheet

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

### Precautionary statements (CLP)

H361d - Suspected of damaging the unborn child.  
H370 - Causes damage to organs (cardiovascular system).  
: 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.  
P271 - Use only outdoors or in a well-ventilated area.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308+P311 - IF exposed or concerned: Call a POISON CENTER or doctor.  
P308+P313 - IF exposed or concerned: Get medical advice/attention.  
P312 - Call a POISON CENTRE or doctor if you feel unwell.  
P321 - Specific treatment (see supplemental first aid instruction on this label).  
P337+P313 - If eye irritation persists: Get medical advice/attention.  
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.  
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

### 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

### 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]
Rizatriptan benzoate	CAS-No.: 145202-66-0	≤ 100	Eye Irrit. 2, H319 Repr. 2, H361d STOT SE 1, H370 STOT SE 3, H336

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.

# Rizatriptan benzoate

## Safety Data Sheet

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

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.

### 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.

# Rizatriptan benzoate

## Safety Data Sheet

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

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

### 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. Crystals.
Molecular mass	: 391,5 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: 178 – 180 °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

# Rizatriptan benzoate

## Safety Data Sheet

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

Viscosity, kinematic	: Not applicable
Solubility	: Water: 33,3 – 100 g/l
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 (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)

### Rizatriptan benzoate (145202-66-0)

LD50 oral rat	2227 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	: Suspected of damaging the unborn child.
STOT-single exposure	: Causes damage to organs (cardiovascular system). May cause drowsiness or dizziness.
STOT-repeated exposure	: Not classified (Lack of data)
Aspiration hazard	: Not classified (Lack of data)

### 11.2. Information on other hazards

No additional information available

# Rizatriptan benzoate

## Safety Data Sheet

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

### 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)

#### Rizatriptan benzoate (145202-66-0)

LC50 - Fish [1]	> 1000 mg/l (96 Hours, Pimephales promelas)
EC50 - Crustacea [1]	1000 mg/l (48 Hours, Daphnia magna (Water flea))
EC50 72h - Algae [1]	> 100 mg/l (72 Hours, Pseudokirchneriella subcapitata (Green algae)) (OECD 201 method)
NOEC chronic fish	9,6 mg/l (32 days, Pimephales promelas) (OECD 210 method)
NOEC chronic crustacea	110 mg/l (21 days, Daphnia magna (Water flea)) (OECD 211 method)
NOEC chronic algae	48 mg/l (72 Hours, Pseudokirchneriella subcapitata (Green algae)) (OECD 201 method)

#### 12.2. Persistence and degradability

#### Rizatriptan benzoate (145202-66-0)

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

#### 12.3. Bioaccumulative potential

#### Rizatriptan benzoate (145202-66-0)

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

#### Rizatriptan benzoate (145202-66-0)

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

#### 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

# Rizatriptan benzoate

## Safety Data Sheet

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

ADR	IMDG	IATA
<b>14.1. UN number or ID number</b>		
Not regulated for transport		
Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>		
Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>		
Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>		
Not regulated	Not regulated	Not regulated
No supplementary information available		

## 14.6. Special precautions for user

### Overland transport

Not regulated

### Transport by sea

Not regulated

### Air transport

Not regulated

## 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)

# Rizatriptan benzoate

## Safety Data Sheet

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

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	Supersedes version of	<b>Added</b>
	Revision date	<b>Added</b>
1.1	CAS-No.	<b>Added</b>
1.1	Synonyms	<b>Removed</b>
1.1	Name	<b>Modified</b>
1.2	Restrictions on use	<b>Modified</b>
1.2	Use of the substance/mixture	<b>Modified</b>
1.2	Main use category	<b>Removed</b>
2.1	Adverse physicochemical, human health and environmental effects	<b>Modified</b>
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<b>Modified</b>
2.2	Hazard statements (CLP)	<b>Modified</b>
2.2	Precautionary statements (CLP)	<b>Modified</b>
2.2	Signal word (CLP)	<b>Modified</b>
2.2	Hazard pictograms (CLP)	<b>Modified</b>
2.3	Other information	<b>Added</b>
4.1	First-aid measures general	<b>Added</b>
4.1	First-aid measures after skin contact	<b>Modified</b>
4.1	First-aid measures after inhalation	<b>Added</b>
4.1	First-aid measures after ingestion	<b>Added</b>
4.1	First-aid measures after eye contact	<b>Modified</b>
4.2	Symptoms/effects after eye contact	<b>Added</b>
5.1	Unsuitable extinguishing media	<b>Added</b>
5.1	Suitable extinguishing media	<b>Modified</b>
5.2	Hazardous decomposition products in case of fire	<b>Added</b>
5.2	Fire hazard	<b>Removed</b>
5.3	Protection during firefighting	<b>Added</b>
5.3	Firefighting instructions	<b>Modified</b>
6.1	Protective equipment	<b>Added</b>
6.1	Emergency procedures	<b>Modified</b>
6.1	General measures	<b>Added</b>
6.2	Environmental precautions	<b>Added</b>
6.3	For containment	<b>Added</b>

# Rizatriptan benzoate

## Safety Data Sheet

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

Indication of changes		
Section	Changed item	Comments
6.3	Methods for cleaning up	<b>Added</b>
6.4	Reference to other sections (8, 13)	<b>Added</b>
7.1	Additional hazards when processed	<b>Added</b>
7.1	Precautions for safe handling	<b>Added</b>
7.1	Hygiene measures	<b>Added</b>
7.2	Storage conditions	<b>Added</b>
7.2	Packaging materials	<b>Added</b>
7.3	Specific end uses	<b>Removed</b>
8.2	Respiratory protection	<b>Added</b>
8.2	Hand protection	<b>Modified</b>
8.2	Eye protection	<b>Added</b>
8.2	Appropriate engineering controls	<b>Modified</b>
8.2	Skin and body protection	<b>Modified</b>
9	Colour	<b>Added</b>
9	Appearance	<b>Modified</b>
9	Solubility in water	<b>Added</b>
9	Molecular mass	<b>Added</b>
9	Melting point	<b>Added</b>
9	Partition coefficient n-octanol/water (Log Kow)	<b>Added</b>
10.1	Reactivity	<b>Removed</b>
10.3	Possibility of hazardous reactions	<b>Removed</b>
10.5	Incompatible materials	<b>Removed</b>
10.6	Hazardous decomposition products	<b>Removed</b>
11.1	LD50 oral rat	<b>Added</b>
11.1	ATE CLP (oral)	<b>Removed</b>
12.1	NOEC chronic crustacea	<b>Added</b>
12.1	NOEC chronic algae	<b>Added</b>
12.1	NOEC chronic fish	<b>Added</b>
12.1	EC50 72h - Algae [1]	<b>Added</b>
12.1	EC50 - Crustacea [1]	<b>Added</b>
12.1	LC50 - Fish [1]	<b>Added</b>
12.1	Ecology - general	<b>Removed</b>

Full text of H- and EUH-statements:	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
H361d	Suspected of damaging the unborn child.

# Rizatriptan benzoate

## Safety Data Sheet

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

Full text of H- and EUH-statements:	
H370	Causes damage to organs (cardiovascular system).
Repr. 2	Reproductive toxicity, Category 2
STOT SE 1	Specific target organ toxicity – single exposure, Category 1
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Narcosis

Safety Data Sheet (SDS), EU

**DISCLAIMER OF LIABILITY** The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. 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 product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable. This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.