



MATERIAL SAFETY DATA SHEET

According to Regulation (EC) No 1907/2006 (REACH) Article 31/Annex II

ratiopharm

eine Marke von
teva

Ranivisio®

Issue Date: 15.09.2022
Revision Date: 15.09.2022

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

1.1. Product identifier

Product name:	Ranivisio®
Substance name:	Ranibizumab
Packaging:	Vial
Concentration:	10 mg/ml

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

Recommended Use:	Formulated pharmaceutical ingredient
Restriction of use:	For professional users only.

1.3. Details of the supplier of the safety data sheet

Company name:	ratiopharm GmbH
Address:	Graf-Arco-Str. 3 D-89079 Ulm Germany
E-mail address:	medical.affairs@teva.de
Telephone number:	+49 (0) 800 800 50 22

1.4. Emergency telephone number

Poisoning Information Centre Freiburg	+49 (0) 761 19 24 0 (24 h reachability)
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.
Based on available data, the classification criteria are not met.

Classification according to Regulation 67/548/EEC / 1999/45/EC

According to present data no classification and labelling is required according to
Directives 67/548/EEC or 1999/45/EC

GHS classification in accordance with 29 CFR 1910.1200

Not a hazardous substance or mixture.



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2.2. Label elements

Labelling according to EC Directives

REGULATION (EC) No 1272/2008

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Handle in accordance with good industrial hygiene and safety practice.

Precautionary statements

P262: Do not get in eyes, on skin, or on clothing.

P280: Wear protective gloves / protective clothing / eye protection / face protection.

67/548/EEC | 1999/45/EC

S-phrase(s)

S24/25: Avoid contact with skin and eyes.

S36: Wear suitable protective clothing.

Labelling in accordance with 29 CFR 1910.1200

Not a hazardous substance or mixture.

2.3. Other hazards

General advice: No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Substances / Mixtures: Mixture

Component	CAS-No.	Concentration %
Ranibizumab	347396-82-1	0.975
Histidine	71-00-1	0.03
Histidine hydrochloride monohydrate	5934-29-2	0.16
α , α -Trehalose dihydrate	6138-23-4	9.635
Polysorbate 20	9005-64-5	0.01
Water for Injection	7732-18-5	89.19



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SECTION 4: First aid measures

4.1. Description of first aid measures

General advice:	Do not leave the victim unattended.
Inhalation:	Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
Skin contact:	After contact with skin, wash immediately with plenty of soap and water. In the case of skin irritation or allergic reactions see a physician.
Eye contact:	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Remove contact lenses. Protect unharmed eye.
Ingestion:	If accidentally swallowed obtain immediate medical attention. Clean mouth with water and drink afterwards plenty of water. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

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

Symptoms:	No information available.
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4.3. Indication of any immediate medical attention and special treatment needed

Treatment:	No information available.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:	Dry powder, Water spray, Foam
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5.2. Special hazards arising from the substance or mixture

Specific hazards during firefighting:	Heating or fire can release toxic gas.
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5.3. Advice for firefighters

Special protective equipment for firefighters:	In the event of fire, wear self-contained breathing apparatus.
Further information:	Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions:	Use respirator when performing operations involving potential exposure to vapour of the product.
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6.2. Environmental precautions

Environmental precautions:	Prevent product from entering drains.
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6.3. Methods and materials for containment and cleaning up

Methods and materials for containment and cleaning up:	Wipe up with absorbent material (e.g. cloth, fleece). Keep in suitable, closed containers for disposal.
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6.4. Reference to other sections

Additional advice:	For personal protection see section 8.
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling:	Provide sufficient air exchange and/or exhaust in work rooms. Smoking, eating and drinking should be prohibited in the application area.
Advice on protection against fire and explosion:	Take precautionary measures against static discharges.



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7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep frozen or refrigerated. To maintain product quality, do not store in heat or direct sunlight. Keep in a dry, cool and wellventilated place.

Packaging material: Suitable material: Glass, Vials

7.3. Specific end use(s)

Specific use(s): No information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Contains no substances with occupational exposure limit values.

8.2. Exposure controls

Personal protective equipment



Respiratory protection: In the case of vapour formation use a respirator with an approved filter.
Respirator with a vapour filter (EN 141) Respirator with ABEK filter.



Hand protection: Suitable material: Nitrile rubber
Break through time : > 480 min
Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).



Eye protection: Tightly fitting safety goggles



Skin and body protection: Choose body protection according to the amount and concentration of the dangerous substance at the work place.
No special protective equipment required.



Hygiene measures: Avoid contact with skin, eyes and clothing.
Wash hands before breaks and immediately after handling the product.



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Environmental exposure controls

General advice: Prevent product from entering drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	Aqueous solution, Sterile liquid
Colour:	colourless, light yellow
pH:	5.2 -5.8
Physical state:	liquid at 2 - 8°C
Flash point:	Does not flash
Flammability (liquids):	Does not sustain combustion
Self-ignition:	Not applicable

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under recommended storage conditions.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Stable under recommended storage conditions.
No hazards to be specifically mentioned.

10.4. Conditions to avoid

No data available

10.5. Incompatible materials

Strong oxidizing agents

10.6. Hazardous decomposition products

No decomposition if stored normally.



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SECTION 11: Toxicological information

11.1. Acute toxicity

Not classified based on available information.

11.2. Reproductive toxicity

Not classified based on available information.

SECTION 12: Ecological information

12.1. Toxicity

Toxicity to fish: No data available

12.2. Persistence and degradability

Biodegradability: No data available

12.3. Bioaccumulative potential

Bioaccumulation: No data available

12.4. Mobility in soil

Behaviour in environmental compartments: No data available

12.5. Results of PBT and vPvB assessment

Assessment: This mixture contains no substance considered to be persistent, bioaccumulating and toxic (PBT). This mixture contains no substance considered to be very persistent and very bioaccumulating (vPvB).

12.6. Other adverse effects

Additional advice: No data available



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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues:	Can be disposed as waste water, when in compliance with local regulations.
Contaminated packagings:	Dispose of as unused product.

SECTION 14: Transport information

IATA: Not regulated as dangerous goods

14.1. UN number: Not applicable
14.2. Proper shipping name: Not applicable
14.3. Transport hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazards: No

IMDG: Not regulated as dangerous goods

14.1. UN number: Not applicable
14.2. Proper shipping name: Not applicable
14.3. Transport hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazards: Marine pollutant: No

ADR: Not regulated as dangerous goods

14.1. UN number: Not applicable
14.2. Proper shipping name: Not applicable
14.3. Transport hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazards: No

RID: Not regulated as dangerous goods

14.1. UN number: Not applicable
14.2. Proper shipping name: Not applicable
14.3. Transport hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazards: No



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DOT: Not regulated as dangerous goods

14.1. UN number: Not applicable
14.2. Proper shipping name: Not applicable
14.3. Transport hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazards: No

TDG: Not dangerous goods

14.1. UN number: Not applicable
14.2. Proper shipping name: Not applicable
14.3. Transport hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazards: Marine pollutant: No

14.6. Special precautions for user: None

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

49 CFR: Not regulated as dangerous goods

SECTION 15: Regulatory information

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

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPO (lbs)
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SARA 311/312 Hazards: No SARA Hazards



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Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A+ B). This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F). This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations Massachusetts

Right To Know Pennsylvania Right To Know

Water	7732-18-5
Trehalose (D+)-, 2H2O	6138-23-4

Maine Chemicals of High Concern Vermont

Chemicals of High Concern Washington

Chemicals of High Concern

The ingredients of this product are reported in the following inventories:

DSL: This product contains the following components that are not on the Canadian DSL nor NDSL.

Ranibizumab

L-Histidine monohydrochloride monohydrate

AICS: Not in compliance with the inventory

NZIoC: On the inventory, or in compliance with the inventory

ENCS: Not in compliance with the inventory



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ISHL:	Not in compliance with the inventory
KECI:	Not in compliance with the inventory
PICCS:	Not in compliance with the inventory
IECSC:	Not in compliance with the inventory
TCSI:	Not in compliance with the inventory
TSCA:	Not in compliance with the inventory
PICCS:	Substance(s) not listed on TSCA inventory

TSCA list

No substances are subject to a Significant New Use Rule.

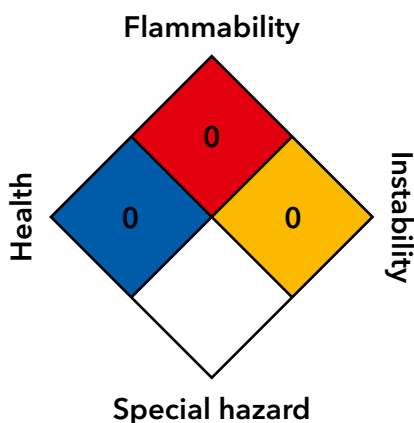
No substances are subject to TSCA 12(b) export notification requirements.

15.2. Chemical Safety Assessment

Not required

SECTION 16: Other information

NFPA:



HMIS® IV:

HEALTH	/	0
FLAMMABILITY		0
PHYSICAL HAZARD		0

HM IS® ratings are based on a 0 – 4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.