

Safety data sheet

classification per Article 31 of Regulation (EC) No. 1907/2006

Valid from: 2019-07-05

Version: 201907_EN_2

replaces version: 201801_EN_1

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

1.1 Product identifier

Brand name: Monoclonal antibody, chimeric

Product no.: MAB-RD

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

Identified use: For laboratory use.

Discouraged uses: No other relevant information available.

1.3 Details of the supplier of the safety data sheet

Institut Virion\Serion GmbH

Friedrich-Bergius-Ring 19

97076 Würzburg

Germany

Tel. 0049 (0) 931 – 30 45 0

Fax 0049 (0) 931 – 30 45 100

Email info@virion-serion.de

1.4 Emergency telephone number

Manufacturer: 0049 (0) 931 – 30 45 0 (Monday to Friday, 8:30 a.m. to 4:00 p.m.)

Section 2: Possible hazards

2.1 Classification of the substance or mixture

Classification per Regulation (EC) No. 1272/2008

Causes skin irritation, Category 2, H315

May cause an allergic skin reaction, Category 1, H317

Causes serious eye irritation, Category 2, H319

2.2 Label elements

Hazard pictogram(s)



Signal word: **Warning**

EUH208: Contains 2-Methyl-2H-isothiazol-3-on. May produce an allergic reaction.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

2.3 Other hazards

This product contains chemically and/or physically inactivated biological agents and should be considered potentially infectious. The mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1 % or higher.

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Section 3: Composition/information on ingredients

3.1 Substance

Not applicable.

3.2 Mixture

2-Mercaptoethanol (< 0.001 %)

EG no.: 200-464-6; CAS no.: 60-24-2

Classification (Regulation (EC) No. 1272/2008):

Fatal in contact with skin, Category 1, H310

Toxic if inhaled, Category 3, H331

Toxic if swallowed, Category 3, H301

Causes skin irritation, Category 2, H315

Causes serious eye damage, Category 1, H318

May cause an allergic skin reaction, Category 1, H317

May cause damage to organs through prolonged or repeated exposure, Category 2, H373

Very toxic to aquatic life, Category 1, H400

Very toxic to aquatic life with long lasting effects, Category 1, H410

Penicillin/Streptomycin (1.0 %)

EG no.: n.a.; CAS no.: n.a.

Classification (Regulation (EC) No. 1272/2008):

Causes skin irritation, Category 2, H315

Causes serious eye irritation, Category 2, H319

May cause an allergic skin reaction, Category 1, H317

May cause respiratory irritation, Category 3, H335

ProClin 300 (0.1 %)

EG no.: n.a.; CAS no.: n.a.

Classification (Regulation (EC) No. 1272/2008):

Toxic in contact with skin, Category 3, H311

Toxic if inhaled, Category 3, H331

Toxic if swallowed, Category 3, H301

Causes severe skin burns and eye damage, Category 1B, H314

May cause an allergic skin reaction, Category 1, H317

Very toxic to aquatic life, Category 1, H400

Very toxic to aquatic life with long lasting effects, Category 1, H410

ProClin 950 (0.15 %)

EG no.: n.a.; CAS no.: n.a.

Classification (Regulation (EC) No. 1272/2008):

Toxic if inhaled, Category 3, H331

Harmful if swallowed, Category 4, H302

Causes severe skin burns and eye damage, Category 1B, H314

May cause an allergic skin reaction, Category 1, H317

May cause respiratory irritation, Category 3, H335

Very toxic to aquatic life, Category 1, H400

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Section 4: First aid measures

4.1 Description of first aid measures

General instructions: Administer artificial respiration for irregular respiration or respiratory arrest. Consult a doctor immediately.

After inhalation: Fresh air or administer oxygen. See a doctor if feeling unwell.

After skin contact: Wash off with plenty of water. Remove contaminated clothing immediately. See a doctor if there are any symptoms.

After eye contact: Flush eyes with plenty of water and intermittently lift the upper and lower eyelids. Check for contact lenses and remove if present. See a doctor if irritation appears.

After swallowing: Rinse out mouth and drink plenty of water. Do not induce vomiting. Consult a doctor if feeling unwell.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indication of any immediate medical attention or special treatment needed

No information available.

Section 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Use extinguishing measures appropriate to the environment.

Unsuitable extinguishing media:

For this substance/mixture there are no limitations on extinguishing agents.

5.2 Special hazards related to this substance or mixture

Non-combustible. In case of fire may be liberated: May produce toxic fumes.

5.3 Advice for firefighters

Special protective equipment for firefighters:

Self-contained breathing apparatus required when in the hazard area. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 Advice for non-emergency personnel

Do not inhale vapors/aerosols. Avoid contact with substance. Ensure adequate ventilation. Evacuate the danger zone, follow the emergency plan, consult specialists.

6.1.2 Information for emergency responders

Protective equipment: see section 8.

6.2 Environmental precautions

No specific procedures required.

6.3 Methods and materials for containment and cleaning up

Remove containers from the discharge area. Avoid discharging in sewer system, bodies of water, basements or closed areas. Take up material and put in appropriately labeled waste containers. Dispose of using an accredited waste disposal company. Clean.

6.4 Reference to other sections

Instructions for disposal see section 13.

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Section 7: Handling and storage

7.1 Precautions for safe handling

7.1.1 Advice on safe handling

Avoid exposure. Follow the instructions on the label.

7.1.2 Hygiene measures

Change contaminated clothing immediately. Apply preventive skin protection. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:

Store only in original container.

7.3 Specific end uses

Apart from the intended use as per section 1.2 no other specific uses are stipulated.

Section 8: Limiting and monitoring exposure/ personal protective equipment

8.1 Parameters to be monitored

No data available.

8.2 Limiting and monitoring exposure

8.2.1 Engineering safety measures

Provide adequate ventilation.

8.2.2 Individual protection

Do not eat, drink or smoke when working. Wash hands before breaks and after working. Use ointment for preventive skin protection.

8.2.2.1 Eye/face protection

Safety goggles.

8.2.2.2 Skin protection

Hand protection

Glove material, e.g. nitrile rubber or butyl rubber.

The protective gloves must conform to the specifications of EC Directive 89/686/EEC and the related standard EN 374.

Other safety precautions

Protective clothing.

8.2.2.3 Respiratory protection

Not necessary.

8.2.3 Limiting and monitoring environmental exposure

No specific procedures required.

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Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	Shape: Liquid. Color: No information available.
Odor	No information available.
Odor threshold	No information available.
pH	No information available.
Melting point	No information available.
Boiling point	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapor pressure	No information available.
Vapor density	No information available.
Relative density	No information available.
Water solubility at 20 °C	No information available.
Partition coefficient: n-octanol/water	No information available.
Auto-ignition temperature	Not applicable.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	No information available.
Oxidizing properties	No information available.

9.2 Other information

No other relevant information available.

Section 10: Stability and reactivity

10.1 Reactivity

No information available.

10.2 Chemical stability

The product is chemically stable under the specified storage conditions.

10.3 Possibility of hazardous reactions

No information available.

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

No information available.

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Section 11: Toxicological information

11.1 Information on toxicological effects

Mixture

Acute oral toxicity

2-Mercaptoethanol (< 0.001 %), LD 50 (oral): 162 mg/kg

Proclin 300 (0.1 %), LD 50 (oral): 300 mg/kg

Proclin 950 (0.15 %), LD 50 (oral): 1962 mg/kg

Calculated estimate of the acute oral toxicity ATE (mix): 242605 mg/kg

Acute inhalation toxicity

2-Mercaptoethanol (< 0.001 %), LC 50 (inhalativ): 1 mg/L/4h

Proclin 300 (0.1 %), LC 50 (inhalative): ATE 3 mg/L/4h

Proclin 950 (0.15 %), LC 50 (inhalative): ATE 3 mg/L/4h

Calculated estimate of the acute inhalative toxicity ATE (mix): 199.843 mg/L/4h

Acute dermal toxicity

2-Mercaptoethanol (< 0.001 %), LD 50 (dermal): 50 mg/kg

Proclin 300 (0.1 %), LD 50 (dermal): 1000 mg/kg.

Calculated estimate of the acute dermal toxicity ATE (mix): 927644 mg/kg

Skin irritation

2-Mercaptoethanol (< 0.001 %) not additive, Category 2

SCL: Category 2: 10 % (general limit value)

Penicillin/Streptomycin (1.0 %) additive, Category 2

Category 2: 10 % (general limit value)

ProClin 300 (0.1 %) additive, Category 1B

Category 1B: 0.6 % Category 1C: 0.6 % Category 2: 0.06 %

The component is classified as relevant.

ProClin 950 (0.15 %) additive, Category 1C

Category 1C: 5 % (general limit value) Category 2: 10 % (general limit value)

The component is classified as not relevant.

The mixture is classified in Category 2.

Eye irritation

2-Mercaptoethanol (< 0.001 %) not additive, Category 1

SCL: Category 1: 3 % (general limit value) Category 2: 10 % (general limit value)

Penicillin/Streptomycin (1.0 %) additive, Category 2

Category 2: 10 % (general limit value)

Sensitization of the skin

2-Mercaptoethanol (< 0.001 %), Category 1

SCL: Category 1: 1 % (general limit value)

Penicillin/Streptomycin (1.0 %), Category 1

Category 1: 1 % (general limit value)

ProClin 300 (0.1 %), Category 1

Category 1: 0.0015 %

ProClin 950 (0.15 %), Category 1B

Category 1B: 1 % (general limit value)

The mixture is classified in Category 1.

Germ cell mutagenicity

No information available.

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Carcinogenicity

No information available.

Reproductive toxicity

No information available.

Teratogenicity

No information available.

Specific target organ toxicity - single exposure: Respiratory

Penicillin/Streptomycin (1.0 %), Category 3

SCL: Category 3: 20 % (general limit value)

ProClin 950 (0.15 %), Category 3

Category 3: 20 % (general limit value)

The mixture is not classified in this category.

Specific target organ toxicity - repeated exposure

No information available.

Aspiration hazard

No information available.

11.2 Further information

Quantitative data on the toxicity of this product are not available.

This product contains chemically inactivated biological agents and should be considered potentially infectious.

Section 12: Ecological information

Mixture

12.1 Toxicity

No information available.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulation potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

There is no PBT/vPvB assessment available because no chemical safety assessment is required/was conducted.

12.6 Other adverse effects

No information available.

Additional ecological information

Discharge into the environment must be avoided.

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Section 13: Disposal considerations

Waste treatment methods

Dispose of leftover product in accordance with Directive 2008/98/EC on Waste and national and regional regulations. Do not mix with other waste. Treat uncleaned containers depending on the product.

Section 14: Transport information

- | | | |
|------|---|--|
| 14.1 | ADR, IMDG, IATA | Not classified as dangerous in the meaning of transport regulations. |
| 14.2 | Proper UN shipping name | Not applicable. |
| 14.3 | Transport hazard class | Not applicable. |
| 14.4 | Packing group | Not applicable. |
| 14.5 | Environmentally hazardous | No. |
| 14.6 | Special precautions for user | No. |
| 14.7 | Transport in bulk according to Annex II of the MARPOL Convention 73/78 and the IBC Code | Not relevant. |

Section 15: Regulatory information

- | | | |
|------|--|-------------|
| 15.1 | Safety, health and environmental regulations/
legislation specific for the substance or mixture | |
| | EU legislation | None known. |
| | National laws | None known. |
| 15.2 | Chemical safety assessment | |
| | A chemical safety assessment has not been conducted for this product. | |

Section 16: Other information

The information describes the product with reference to the applicable safety precautions. It is not an assurance of the properties of the product.