

Safety data sheet

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

Valid from: 20160601

Version: 201607_8_1 replaces version dated: 20130308

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

1.1 Product identifier

Brand name: SERION KBR Antigens

Product no.: 11xx, 12xx, 13xx, 9060, 9070, 9080, 9100, 9110, 9120

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

Identified use:

In vitro diagnostic agent or component of in vitro diagnostic agent

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 am to 4:00 pm)

Section 2: Possible hazards

2.1 Classification of the substance or mixture

Classification per Regulation (EC) No. 1272/2008

Acute dermal toxicity, category 4, H312

Water hazard: Chronic, category 3, H412

2.2 Label elements

Hazard pictogram(s)



Signal word: **Caution**

H statements:

H312: Harmful in contact with skin.

H412: Harmful to aquatic life with long-lasting effects.

P statements:

P273: Avoid release to the environment.

P280: Wear protective gloves/protective clothing.

P302 + P352: IF ON SKIN: Wash with plenty of water and soap.

P312: Call a POISON CENTER or doctor if you feel unwell.

P501: Dispose of contents/container to an approved disposal company.

2.3 Other hazards

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

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Section 3: Composition/information on ingredients

3.1 Substance

Not applicable

3.2 Mixture

Thiomersal

EC No.: 200-210-4; Index number: 080-004-00-7; CAS no. 45-64-8

Percentage: <0.3%

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

Acute tox. 1; H310 Fatal in contact with skin.

Acute tox. 2; H330 Fatal if inhaled.

STOT RE 2; H373 May cause damage to organs through prolonged or repeated exposure.

Aquatic Acute 1; H400 Very toxic to aquatic life.

Aquatic Chronic 1; H410 Very toxic to aquatic life with long-lasting effects.

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. Consult doctor.

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

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. Consult doctor.

After swallowing: Rinse out mouth and drink plenty of water (max. 2 glasses). 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

Not combustible. Heating or fire may release hazardous gases. Sulfur oxides (SOx) may be released in case of fire. A fire in the nearby surroundings may generate hazardous vapors.

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. Fire residues and contaminated extinguishing water must be disposed of in accordance with legal requirements.

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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

Do not allow discharge in sewer system.

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.

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. Ensure good ventilation and extraction. Open containers carefully.

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. Prevent leakage into soil.

7.3 Specific end uses

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

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Section 8: Limiting and monitoring exposure/ personal protective equipment

8.1 Parameters to be monitored

Constituents with workplace-related limit values that must be monitored

Thiomersal (CAS no. 54-64-8)	
MWC	Section IV

8.2 Limiting and monitoring exposure

8.2.1 Engineering safety measures

Ensure good general ventilation at the workplace.

8.2.2 Individual protection

Do not eat, drink or smoke when working. Wash hands before breaks and after working. Avoid contact with clothing. Remove contaminated clothing and clean thoroughly. Change work clothing before breaks if necessary.

8.2.2.1 Eye/face protection

Adequate eye protection should be worn.
Use framed glasses with a side shield.

8.2.2.2 Skin protection

Hand protection

The glove material must be impermeable and resistant to the product/substance/preparation. Select glove material with reference to penetration times, permeation rates and degradation.

Glove material

The selection of a suitable glove depends not only on the material but also on other quality features and varies from manufacturer to manufacturer.

Penetration time of the glove material

The exact penetration time must be specified by the glove manufacturer and must be observed.

Gloves of the following materials are suitable for continuous contact:

Nitrile rubber

Recommended thickness: ≥ 0.11 mm

Value for permeation: Level ≥ 480 min

Gloves of the following materials are suitable for spray protection:

Nitrile rubber

Recommended thickness: ≥ 0.11 mm

Value for permeation: Level ≥ 480 min

Other safety precautions

Select suitable protection equipment for the workplace depending on the concentration and volume of the hazardous substance.

8.2.2.3 Respiratory protection

Respiratory protection is required if dust is generated.

Respiratory filter device for short-term or low volumes; self-contained breathing apparatus for intensive or extended exposure.

Respiratory protection is required if dust is generated.

Special gas filter Hg-P38.

8.2.3 Limiting and monitoring environmental exposure

Do not allow discharge in sewer system. Discharge into the environment must be avoided.

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Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	shape: solid pellet Color: yellowish white or light violet
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	soluble
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

In the event of fire, sulfur oxides (SO_x) may form.

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Section 11: Toxicological information

11.1 Information on toxicological effects

Mixture

Acute oral toxicity

No information available.

Acute inhalation toxicity

No information available.

Acute dermal toxicity

No information available.

Skin irritation

No information available.

Eye irritation

No information available.

Sensitization

No information available.

Germ cell mutagenicity

No information available.

Carcinogenicity

No information available.

Reproductive toxicity

No information available.

Teratogenicity

No information available.

Specific target organ toxicity - single exposure

No information available.

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.

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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.

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 UN number not classified as dangerous goods as per ADR/RID (land transport), IATA (air transport) and IMDG (marine transport).

14.2 Proper UN shipping name not applicable

14.3 Transport hazard class not applicable

14.4 Packing group not applicable

14.5 Environmental hazard no

14.6 Special precautions for users 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.

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Section 16: Other information

Full text of hazard warnings in section 3.2:

H statements:

H312: Harmful in contact with skin.

H412: Harmful to aquatic life with long-lasting effects.

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