

Safety data sheet

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

Valid from: 2017-12-01

Version: 201712_3_EN_2

replaces version dated: 2017-08-01

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

1.1 Product identifier

Brand name: FSME Virus Antigen (Premium)

Product no.: BA112VS

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

Identified use: In vitro diagnostic agent or component of an 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 dialog@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

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

2.2 Label elements

The product does not need to be labelled in accordance with EC directives or respective national laws.

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.

Section 3: Composition/information on ingredients

3.1 Substance

Not applicable

3.2 Mixture

Component **MOPS (3-(N-Morpholino)propanesulfonic acid)** (fraction: < 1 %):

EG no.: 214-478-5;

INDEX no.: 214-478-5;

CAS no.: 1132-61-2

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

- Causes skin irritation, Category 2, H315
- Causes serious eye irritation, Category 2, H319
- May cause respiratory irritation, Category 3, H335

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Component **Triton X-100** (fraction: < 1 %):

EG no.: n.a.;

INDEX no.: 604-075-00-6;

CAS no.: 9002-93-1

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

- Harmful if swallowed, Category 4, H302
- Causes skin irritation, Category 2, H315
- Causes serious eye damage, Category 1, H318
- Toxic to aquatic life with long lasting effects, Category 2, H411

SVHC

CAS: 9002-93-1 Triton X-100

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 a doctor.

After skin contact: Wash off with plenty of water. Consult a doctor.

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 a doctor.

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

Component MOPS (< 1 %):

No information available.

Component Triton X-100 (< 1 %):

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.

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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

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.

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

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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.

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.

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10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

No information available.

10.6 Hazardous decomposition products

Under fire conditions, formation of Sulphur oxides (SOx) possible.

Section 11: Toxicological information

11.1 Information on toxicological effects

Mixture

Acute oral toxicity

Triton X-100 (< 1 %), LD 50 (oral): ATE 500 mg/kg

Calculated estimate of the acute oral toxicity ATE (mix): 500000 mg/kg

Acute inhalation toxicity

No information available.

Acute dermal toxicity

No information available.

Skin irritation

Relevant Components:

MOPS (<1 %) not additive, Category 2

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

Triton X-100 (<1 %) not additive, Category 2

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

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: Respiratory

Relevant Components:

MOPS (<1 %), Category 3

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

The mixture is not classified in this category.

Specific target organ toxicity - repeated exposure

No information available.

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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

Components that may contribute to eutrophication of water supplies:

Triton X-100 (0,1 %), Category 2, LC50(fish): 4 mg/l

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 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*

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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 Water hazard class: WHC 1 (self-rating): weakly hazardous to water

Other Regulations contains substances of very concern (SVHC) according to REACH, Article 57:

CAS no.: 9002-93-1 (4-(1,1,3,3-Tetramethylbutyl)phenyl-polyethylene glycol) Triton X-100

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.