

Safety data sheet

according to Article 32 of Regulation (EC) No. 1907/2006 and (EU) 2015/830

Valid from: 20181001

Version: 201809_20_1 replaces version dated: First version

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

1.1 Product identifier

Trade name: Haemolytic System for CFT

Product no.: HS-020, HS-023, HS-050, HS-053, HS-100, HS-103

1.2 Relevant identified uses of the substance or mixture and discouraged uses

Identified use: In vitro diagnostic agent or component of an in vitro diagnostic agent

Discouraged uses: No other relevant data 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: 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 EC Regulation No. 1272/2008.

2.2 Label elements

This product does not need to be labelled in accordance with EC Directives or applicable national laws.

2.3 Other hazards

This product contains chemically and/or physically inactivated biological agents and should be considered potentially infectious. This mixture does not meet the criteria to be classified as PBT or vPvB.

Section 3: Composition/information on ingredients

3.1 Substance

Not applicable

3.2 Mixture

Stabilisation buffer (99%); sheep red blood cells (1%); amboceptor (< 0.1%)

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Section 4: First aid measures

4.1 Description of first aid measures

Following inhalation:	Fresh air. Consult a doctor if feeling unwell.
Following skin contact:	Wash off with plenty of water. Remove contaminated clothing immediately. Treat affected areas with skin disinfectant. See a doctor if there are any symptoms.
Following 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 if irritation occurs.
Following ingestion:	Rinse out mouth and drink plenty of water. 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 and 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

There are no restrictions for the extinguishing media used for this substance/mixture.

5.2 Special hazards arising from the substance or mixture

Non-flammable. A fire in the nearby surroundings may generate hazardous vapours.

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 Information for non-emergency personnel

Do not breathe vapour/aerosol. 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 empty into drains.

6.3 Methods and materials for containment and cleaning up

Remove containers from the discharge area. Avoid discharging into the sewer system, bodies of water, basements or closed areas. Collect the material and put in appropriately labelled waste containers. Dispose of through 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 vessels:

Keep only in the original container.

7.3 Specific end uses

Apart from the intended use as per Section 1.2, no other specific end uses are stipulated.

Section 8: Exposure controls/ Personal protective equipment

8.1 Control parameters

Does not contain substances with occupational exposure limits.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Ensure good general ventilation at the workplace.

8.2.2 Personal protection measures

When using do not eat, drink or smoke. Wash hands before breaks and after work. Apply preventive skin protection.

8.2.2.1 Eye/face protection

Safety glasses

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 required.

8.2.3 Environmental exposure controls

No special precautions required.

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Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	Physical state: Liquid
	Colour: red
Odour	Characteristic
Odour threshold	No information available.
pH	Not applicable.
Melting point	No information available.
Boiling point	No information available.
Flash point	Not applicable.
Evaporation rate	No information available.
Flammability (solid, gas)	Not applicable.
Lower explosion limit	Not applicable.
Upper explosion limit	Not applicable.
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	No information available
Water solubility at 20 °C	Not applicable.
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	Not classified as explosive.
Oxidising properties	None

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

No information available.

Acute inhalative toxicity

No information available.

Acute dermal toxicity

No information available.

Skin irritation

No information available.

Eye irritation

No information available.

Sensitisation

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 Other information

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

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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.

Ingredients

No data available.

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. Handle uncleaned containers like the product itself.

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 none

14.6 Special precautions for user none

14.7 Transport in bulk according to Annex II of the MARPOL Convention 73/78 and the IBC Code

Not relevant

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Section 15: Regulatory information

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

EU regulations

Directive 96/82/EC (On the Control of Major-Accident Hazards Involving Dangerous Substances):

Directive 96/82/EC does not apply.

Employment restrictions:

The employment restrictions set down in the German Youth Employment Protection Act (94/33/EG) must be observed.

National regulations

Water hazard class:

Not a water hazard as per VwVwS (Administrative Regulation on Substances Hazardous to Waters)

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.