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

1.1 Product identifier
Trade name: SERION ELISA classic Kit
Product no.: ESRxxxxx

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
E-Mail 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, mixture or product
Classification according to Regulation (EC) No. 1272/2008
Does not contain any hazardous substance or mixture as per 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
Does not contain any hazardous ingredients as per EC Regulation No. 1272/2008.
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 inhale vapours/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 special precautions required.

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.
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:
Store only in 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 protection/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
Do not eat, drink or smoke when working. 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

Other safety precautions
Protective clothing

8.2.3 Respiratory protection
Not required.

8.2.3 Environmental exposure controls
No special precautions required.
Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
Appearance Physical state: Kit with various components
Odour Not applicable
Odour threshold Not applicable
pH Not applicable
Melting point Not applicable
Boiling point Not applicable
Flash point Not applicable
Evaporation rate Not applicable
Flammability (solid, gas) Not applicable
Lower explosion limit Not applicable
Upper explosion limit Not applicable
Vapour pressure Not applicable
Vapour density Not applicable
Relative density Not applicable
Water solubility at 20 °C Not applicable
Partition coefficient: n-octanol/water Not applicable
Auto-ignition temperature Not applicable
Decomposition temperature Not applicable
Viscosity, dynamic Not applicable
Explosive properties Not applicable
Oxidising properties Not applicable

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.
Section 11: Toxicological information

11.1 Information on toxicological effects

Product

**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.

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.

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
Section 15: Regulatory information

15.1 Safety, health and environmental regulations/
     legislation specific for the substance or mixture
     EU regulations none known
     National regulations 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.