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

1.1 Product identifier

Trade name: SERION ELISA agile SARS-CoV-2 IgG
Product no: ESR400G

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, mixture or product according to EC Regulation 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.
After contact with the skin:	Wash off with plenty of water. Remove contaminated clothing immediately. Treat affected areas with skin disinfectant. See a doctor if there are any symptoms.
After contact with the eyes:	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 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
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

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:
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: Limiting and monitoring exposure/Personal protective equipment

8.1 Control parameters
Does not contain substances with occupational exposure limits.

8.2 Limiting and monitoring exposure

8.2.1 Engineering safety measures
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 a barrier ointment as 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 Limiting and monitoring environmental exposure
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: Instructions for disposal

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 to 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.