

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 12 Apr 2024

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Version: 1

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

1.1. Product identifier

Trade name/designation:

SERION ELISA antigen Kit

Article No.:

ESR200

UFI:

N9E0-11JV-F384-K287

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

Use of the substance/mixture:

The product is intended for professional use.

1.3. Details of the supplier of the safety data sheet

Supplier (manufacturer/importer/only representative/downstream user/distributor):

Institut Virion\Serion GmbH

Productmanagement

Friedrich-Bergius-Ring 19

97076 Würzburg

Germany

Telephone: +49 931 3045 0

Telefax: +49 931 3045 100

E-mail: product.safety@virion-serion.de

Website: www.virion-serion.de

E-mail (competent person): product.safety@virion-serion.de

1.4. Emergency telephone number

Institut Virion\Serion GmbH, Friedrich-Bergius-Ring 19; 97076 Würzburg, Germany, +49 931 3045 0 (Only available during office hours.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

Hazard classes and hazard categories	Hazard statements	Classification procedure
Corrosive to metals (<i>Met. Corr. 1</i>)	H290: May be corrosive to metals.	
Respiratory or skin sensitisation (<i>Skin Sens. 1</i>)	H317: May cause an allergic skin reaction.	
Reproductive toxicity (<i>Repr. 1B</i>)	H360D: May damage the unborn child.	

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms:



GHS05

Corrosion



GHS07

Exclamation mark



GHS08

Health hazard

Signal word: Danger

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Hazard components for labelling:
ProClin 300; 2-pyrrolidone; sulphuric acid; hydrogen chloride

Hazard statements for physical hazards	
H290	May be corrosive to metals.
Hazard statements for health hazards	
H317	May cause an allergic skin reaction.
H360D	May damage the unborn child.

Supplemental hazard information: none

Precautionary statements Prevention	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing and eye protection/face protection.
Precautionary statements Response	
P302 + P352	IF ON SKIN: Wash with plenty of water and soap.
P308 + P313	IF exposed or concerned: Get medical advice/attention.

2.3. Other hazards
No data available

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
CAS No.: 7647-01-0 EC No.: 231-595-7 Index No.: 017-002-01-X REACH No.: 01-2119484862-27-XXXX	hydrogen chloride Eye Irrit. 2 (H319), Met. Corr. 1 (H290), STOT SE 3 (H335), Skin Irrit. 2 (H315) Warning Specific concentration limit (SCL) Met. Corr. 1; H290: C ≥ 0.1% Skin Corr. 1B; H314: C ≥ 25% Skin Irrit. 2; H315: 10% ≤ C < 25% Eye Dam. 1; H318: C ≥ 25% Eye Irrit. 2; H319: 10% ≤ C < 25% STOT SE 3; H335: C ≥ 10%	0 - < 1 weight-%
CAS No.: 7664-93-9 EC No.: 231-639-5 Index No.: 016-020-00-8 REACH No.: 01-2119458838-20	sulphuric acid Eye Dam. 1 (H318), Met. Corr. 1 (H290), Skin Corr. 1A (H314) Danger Specific concentration limit (SCL) Skin Corr. 1A; H314: C ≥ 15% Skin Irrit. 2; H315: 5% ≤ C < 15% Eye Dam. 1; H318: C ≥ 15% Eye Irrit. 2; H319: 5% ≤ C < 15%	0 - < 1 weight-%
CAS No.: 616-45-5 EC No.: 210-483-1 REACH No.: 01-2119475471-37	2-pyrrolidone Eye Irrit. 2 (H319), Repr. 1B (H360D) Danger	0 - < 0.3 weight-%

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Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
CAS No.: 55965-84-9 EC No.: 911-418-6 REACH No.: 01-2120764691-48-XXXX	ProClin 300 Acute Tox. 2 (H330, H310), Acute Tox. 3 (H301), Aquatic Chronic 1 (H410), Eye Dam. 1 (H318), Skin Corr. 1C (H314), Skin Sens. 1A (H317)    Danger M-factor (acute): 100 Specific concentration limit (SCL) Skin Corr. 1C; H314: $C \geq 0.6\%$ Skin Irrit. 2; H315: $0.06\% \leq C < 0.6\%$ Eye Dam. 1; H318: $C \geq 0.6\%$ Eye Irrit. 2; H319: $0.06\% \leq C < 0.6\%$ Skin Sens. 1A; H317: $C \geq 0.0015\%$	0 - \leq 0.1 weight-%
CAS No.: 26628-22-8 EC No.: 247-852-1	sodium azide Substance with a community workplace exposure limit.	0 - \leq 0.1 weight-%

Full text of H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

Following inhalation:

Provide fresh air. In case of respiratory tract irritation, consult a physician. Get medical advice/attention if you feel unwell.

In case of skin contact:

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.

Following ingestion:

Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

Self-protection of the first aider:

Use personal protection equipment. No direct artificial respiration to be given by first aider.

4.2. Most important symptoms and effects, both acute and delayed

Allergic reactions

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

No data available

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products:

In case of fire: Gases/vapours, toxic

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Personal precautions:

Remove persons to safety.

Protective equipment:

Wear protective gloves/protective clothing/eye protection/face protection.

6.1.2. For emergency responders

Personal protection equipment:

Personal protection equipment: see section 8

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment:

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

6.5. Additional information

Use appropriate container to avoid environmental contamination.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures

Advices on safe handling:

Wear personal protection equipment (refer to section 8). Avoid contact during pregnancy/while nursing.

Advices on general occupational hygiene

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

7.3. Specific end use(s)

No data available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Occupational exposure limit values

Limit value type (country of origin)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
IOELV (EU)	hydrogen chloride CAS No.: 7647-01-0 EC No.: 231-595-7	① 5 ppm (8 mg/m ³) ② 10 ppm (15 mg/m ³) ⑤ (Hydrogen chloride)
WEL (GB)	hydrogen chloride CAS No.: 7647-01-0 EC No.: 231-595-7	① 1 ppm (2 mg/m ³) ② 5 ppm (8 mg/m ³) ⑤ (gas and aerosol mists)

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Limit value type (country of origin)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
IOELV (EU)	sulphuric acid CAS No.: 7664-93-9 EC No.: 231-639-5	① 0.05 mg/m ³
WEL (GB) from 18 Dec 2011	sulphuric acid CAS No.: 7664-93-9 EC No.: 231-639-5	① 0.05 mg/m ³ ⑤ (The mist is defined as the thoracic fraction)
WEL (GB)	sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	① 0.1 mg/m ³ ② 0.3 mg/m ³ ⑤ (may be absorbed through the skin)
IOELV (EU)	sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	① 0.1 mg/m ³ ② 0.3 mg/m ³ ⑤ (may be absorbed through the skin)

8.1.2. Biological limit values

No data available

8.1.3. DNEL-/PNEC-values

Substance name	DNEL value	① DNEL type ② Exposure route
sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	0.0164	① DNEL worker ② Long-term - inhalation, systemic effects
sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	0.0467	① DNEL worker ② Long-term - dermal, systemic effects
sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	0.0167	① DNEL worker ② Long-term - oral, systemic effects

Substance name	PNEC Value	① PNEC type
Ethylendiamin-tetraessigsäure Dinatriumsalz CAS No.: 6381-92-6 EC No.: 205-358-3	2.2 mg/L	① PNEC aquatic, freshwater
Ethylendiamin-tetraessigsäure Dinatriumsalz CAS No.: 6381-92-6 EC No.: 205-358-3	0.22 mg/L	① PNEC aquatic, marine water
Ethylendiamin-tetraessigsäure Dinatriumsalz CAS No.: 6381-92-6 EC No.: 205-358-3	43 mg/L	① PNEC sewage treatment plant
sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	0.00035 mg/L	① PNEC aquatic, freshwater
sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	0.000015 mg/L	① PNEC aquatic, marine water
sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	0.0167 mg/kg	① PNEC sediment, freshwater
sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1	0.00072 mg/kg	① PNEC sediment, marine water

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8.2. Exposure controls

8.2.1. Appropriate engineering controls

No data available

8.2.2. Personal protection equipment

Eye/face protection:

Eye glasses with side protection EN 166

Skin protection:

Tested protective gloves must be worn EN ISO 374 Suitable material: NBR (Nitrile rubber) Breakthrough time: 480 min In the case of wanting to use the gloves again, clean them before taking off and air them well. Breakthrough times and swelling properties of the material must be taken into consideration.

8.2.3. Environmental exposure controls

No data available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Liquid

Colour: not determined

Odour: not determined

Safety relevant basis data

Parameter	Value	① Method ② Remark
pH	not applicable	
Melting point	No data available	
Freezing point	No data available	
Initial boiling point and boiling range	No data available	
Flash point	No data available	
Evaporation rate	No data available	
Auto-ignition temperature	No data available	
Upper/lower flammability or explosive limits	No data available	
Vapour pressure	No data available	
Vapour density	No data available	
Density	No data available	
Bulk density	not applicable	
Water solubility	No data available	
Dynamic viscosity	No data available	
Kinematic viscosity	No data available	

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

May be corrosive to metals.

10.2. Chemical stability

No data available

10.3. Possibility of hazardous reactions

No data available

10.4. Conditions to avoid

No data available

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10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

No data available

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

sulphuric acid	CAS No.: 7664-93-9	EC No.: 231-639-5
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LD₅₀ oral:	2,140 mg/kg (Ratte)
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LC₅₀ Acute inhalation toxicity (vapour):	510 mg/L 2 h (Ratte)
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2-pyrrolidone	CAS No.: 616-45-5	EC No.: 210-483-1
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LD₅₀ oral:	>2,000 mg/kg (Ratte)
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LD₅₀ dermal:	>2,000 mg/kg (Kaninchen)
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ProClin 300	CAS No.: 55965-84-9	EC No.: 911-418-6
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LD₅₀ oral:	66 mg/kg (Rat)
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LD₅₀ dermal:	87.12 mg/kg (Rabbit) ECHA
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LC₅₀ Acute inhalation toxicity (dust/mist):	0.171 mg/L (Rat)
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sodium azide	CAS No.: 26628-22-8	EC No.: 247-852-1
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LD₅₀ oral:	27 mg/kg (Rat)
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LD₅₀ dermal:	18 mg/kg (Rabbit)
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LC₅₀ Acute inhalation toxicity (dust/mist):	5.4 mg/L 4 h (Rat)
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Acute oral toxicity:

Based on available data, the classification criteria are not met.

Acute dermal toxicity:

Based on available data, the classification criteria are not met.

Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

Serious eye damage/irritation:

Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation:

May cause an allergic skin reaction.

Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

Carcinogenicity:

Based on available data, the classification criteria are not met.

Reproductive toxicity:

Based on available data, the classification criteria are not met. May damage the unborn child.

STOT-single exposure:

Based on available data, the classification criteria are not met.

STOT-repeated exposure:

Based on available data, the classification criteria are not met.

Aspiration hazard:

Based on available data, the classification criteria are not met.

Additional information:

No data available

11.2. Information on other hazards

No data available

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SECTION 12: Ecological information

12.1. Toxicity

sulphuric acid CAS No.: 7664-93-9 EC No.: 231-639-5

EC₅₀: 1.2 mg/L 4 d

2-pyrrolidone CAS No.: 616-45-5 EC No.: 210-483-1

LC₅₀: 10,000 mg/L 4 d (fish, Danio rerio (zebrafish)) OECD 203

EC₅₀: >500 mg/L 2 d (Daphnia magna)

EC₅₀: >1,000 mg/L (Algae/water plant, Mikroorganismen)

ErC₅₀: >500 mg/L 3 d (Algae/water plant, Desmodesmus subspicatus)

EC₅₀: >500 mg/L 2 d (crustaceans, Daphnia magna (Big water flea))

ProClin 300 CAS No.: 55965-84-9 EC No.: 911-418-6

LC₅₀: 0.16 mg/L 4 d (Oncorhynchus mykiss (Rainbow trout))

LC₅₀: 0.18 mg/L 2 d (Daphnia magna (Big water flea))

LC₅₀: 0.19 mg/L 4 d (fish)

EC₅₀: 4.8 mg/L (Activated sludge)

EC₅₀: 0.18 mg/L 2 d (crustaceans)

EC₅₀: 0.13 mg/L 3 d (Algae/water plant)

NOEC: 0.098 mg/L 33 d (Oncorhynchus mykiss (Rainbow trout))

NOEC: 0.1 mg/L 21 d (Daphnia magna (Big water flea))

sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1

EC₅₀: 0.348 mg/L 4 d (Algae/water plant)

12.2. Persistence and degradability

sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1

Biodegradation: —

12.3. Bioaccumulative potential

2-pyrrolidone CAS No.: 616-45-5 EC No.: 210-483-1

Log K_{ow}: -0.71

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

hydrogen chloride CAS No.: 7647-01-0 EC No.: 231-595-7

Results of PBT and vPvB assessment: —

sulphuric acid CAS No.: 7664-93-9 EC No.: 231-639-5

Results of PBT and vPvB assessment: —

2-pyrrolidone CAS No.: 616-45-5 EC No.: 210-483-1

Results of PBT and vPvB assessment: —

ProClin 300 CAS No.: 55965-84-9 EC No.: 911-418-6

Results of PBT and vPvB assessment: —

sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1

Results of PBT and vPvB assessment: —

12.6. Endocrine disrupting properties

No data available

12.7. Other adverse effects

No data available

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SECTION 13: Disposal considerations





13.1. Waste treatment methods

Waste treatment options

Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1. UN number or ID number			
UN 1760	UN 1760	UN 1760	UN 1760
14.2. UN proper shipping name			
CORROSIVE LIQUID, N.O.S.	CORROSIVE LIQUID, N.O.S.	CORROSIVE LIQUID, N.O.S.	CORROSIVE LIQUID, N.O.S.
14.3. Transport hazard class(es)			
 8	 8	 8	 8
14.4. Packing group			
III	III	III	III
14.5. Environmental hazards			
No	No	No	No
14.6. Special precautions for user			
Special Provisions: 274 Limited quantity (LQ): 5 L Excepted Quantities (EQ): E1 Hazard identification number (Kemler No.): 80 Classification code: C9 Tunnel restriction code: (E)	Special Provisions: 274 Limited quantity (LQ): 5 L Excepted Quantities (EQ): E1 Classification code: C9	Special Provisions: 223 274 Limited quantity (LQ): 5 L Excepted Quantities (EQ): E1 EmS-No.: F-A, S-B	Special Provisions: A3 Limited quantity (LQ): Y841 Excepted Quantities (EQ): E1

14.7. Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

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

No data available

15.2. Chemical Safety Assessment

No data available

SECTION 16: Other information

16.1. Indication of changes

No data available

16.2. Abbreviations and acronyms

ACGIH American Conference of Governmental Industrial Hygienists

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ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging
DIN	German Institute for Standardization / German Industrial Standard
DNEL	derived no-effect level
EC ₅₀	Effective Concentration 50%
ECHA	European Chemicals Agency
EN	European Standard
ES	Exposure scenario
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Standards Organisation
LC ₅₀	Lethal (fatal) Concentration 50%
LD ₅₀	Lethal (fatal) Dose 50%
MAK	Maximum concentration in the workplace air (CH)
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety & Health
NOEC	No Observed Effect Concentration
OECD	Organisation for Economic Cooperation and Development
OSHA	Occupational Safety & Health Administration
PBT	persistent and bioaccumulative and toxic
PNEC	Predicted No Effect Concentration
REACH	Registration, Evaluation and Authorization of Chemicals
RID	Dangerous goods regulations for transport by rail
SCL	Specific concentration limit
TRGS	Technische Regeln für Gefahrstoffe
UN	United Nations

16.3. Key literature references and sources for data

No data available

16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

Hazard classes and hazard categories	Hazard statements	Classification procedure
Corrosive to metals (<i>Met. Corr. 1</i>)	H290: May be corrosive to metals.	
Respiratory or skin sensitisation (<i>Skin Sens. 1</i>)	H317: May cause an allergic skin reaction.	
Reproductive toxicity (<i>Repr. 1B</i>)	H360D: May damage the unborn child.	

16.5. List of relevant hazard statements and/or precautionary statements from sections 2 to 15

Hazard statements	
H290	May be corrosive to metals.
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H335	May cause respiratory irritation.
H360D	May damage the unborn child.
H410	Very toxic to aquatic life with long lasting effects.

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16.6. Training advice

No data available

16.7. Additional information

No data available