SERION ELISA AI control

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

1.1. Product identifier

Trade name/designation:

SERION ELISA AI control

Article No.:
CLS*

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
Email: product.safety@virion-serion.de
Website: www.virion-serion.de

Email (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]
The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]
According to EC directives or the corresponding national regulations the product does not have to be labelled.
Hazard statements: none
Supplemental hazard information: none
Precautionary statements: none

* 2.3. Other hazards

Other adverse effects:
This product contains components of human origin. The human source material has been tested for HIV antibodies, HBsAg and HCV and found to be non-reactive. However, as no test method can provide complete assurance of the absence of infectious agents, this material should be handled as potentially infectious and disposed of in accordance with applicable regulations.
This substance/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

* **3.2. Mixtures**

Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
CAS No.: 26628-22-8 EC No.: 247-852-1 Index No.: 011-004-00-7	**sodium azide** Acute Tox. 2 (H300), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410)  Danger EUH032 **Acute Toxicity Estimate** ATE (oral) 27 mg/kg ATE (dermal) 18 mg/kg ATE (inhalation, dust/mist) 5.4 mg/L	0 – ≤ 0.09 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.

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

4.2. Most important symptoms and effects, both acute and delayed
No known symptoms to date.

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

SECTION 5: Firefighting measures

* **5.1. Extinguishing media**

Suitable extinguishing media:
Co-ordinate fire-fighting measures to the fire surroundings.

Unsuitable extinguishing media:
Full water jet

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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Personal precautions:
Avoid breathing dust/fume/gas/mist/vapours/spray. 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).

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
WEL (GB)	**D(+)-Saccharose** CAS No.: 57-50-1 EC No.: 200-334-9	① 10 mg/m³ ② 20 mg/m³
WEL (GB)	**sodium azide** CAS No.: 26628-22-8 EC No.: 247-852-1	① 0.1 mg/m³ ② 0.3 mg/m³ 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/m³ ② 0.3 mg/m³ 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
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

*
8.2. Exposure controls

8.2.1. Appropriate engineering controls
No data available

8.2.2. Personal protection equipment



Eye/face protection:
Use safety goggle with side protection: EN ISO 16321-1:2022

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: solid
Colour: not determined
Odour: not determined
flammability: No data available

Safety relevant basis data

Parameter	Value	① Method ② Remark
pH	*No data available*	
Melting point	*No data available*	

Parameter	Value	① Method ② Remark
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
No data available

10.2. Chemical stability
No data available

10.3. Possibility of hazardous reactions
No data available

10.4. Conditions to avoid
No data available

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

sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1
LD_{50} oral: 27 mg/kg (Rat)
LD_{50} dermal: 18 mg/kg (Rabbit)
LC_{50} Acute inhalation toxicity (dust/mist): 5.4 mg/L 4 h (Rat)

Acute oral toxicity:
Shall not be classified as acutely toxic.

Acute dermal toxicity:
Shall not be classified as acutely toxic.

Acute inhalation toxicity:
Shall not be classified as acutely toxic.

Skin corrosion/irritation:
Shall not be classified as corrosive/irritant to skin.

Serious eye damage/irritation:
Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation:
Shall not be classified as a respiratory or skin sensitiser

Germ cell mutagenicity:
Shall not be classified as germ cell mutagenic.

Carcinogenicity:
Shall not be classified as carcinogenic.

Reproductive toxicity:
Shall not be classified as a reproductive toxicant.

STOT-single exposure:
Shall not be classified as a specific target organ toxicant (single exposure).

STOT-repeated exposure:
Shall not be classified as a specific target organ toxicant (repeated exposure).

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

Additional information:
No data available

* 11.2. Information on other hazards

Endocrine disrupting properties:
Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0.1%.

SECTION 12: Ecological information

* 12.1. Toxicity

sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1
EC_{50}: 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
No data available

12.4. Mobility in soil
No data available

* 12.5. Results of PBT and vPvB assessment

sodium azide CAS No.: 26628-22-8 EC No.: 247-852-1
Results of PBT and vPvB assessment: —

This substance/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.

* 12.6. Endocrine disrupting properties
Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0.1%.

12.7. Other adverse effects
No data available

SECTION 13: Disposal considerations

* 13.1. Waste treatment methods
Product residues must be disposed of in accordance with national and regional regulations. Consult the appropriate local waste disposal expert about waste disposal.

GeSi.de

13.1.1. Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV
Directive 2008/98/EC (Waste Framework Directive)

HP 12	Release of an acute toxic gas

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			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
* **14.3. Transport hazard class(es)**			
not relevant	not relevant	not relevant	not relevant
14.4. Packing group			
not relevant	not relevant	not relevant	not relevant
14.5. Environmental hazards			
not relevant	not relevant	not relevant	not relevant
14.6. Special precautions for user			
not relevant	not relevant	not relevant	not relevant

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

1.3.	Details of the supplier of the safety data sheet
1.4.	Emergency telephone number
2.3.	Other hazards
3.2.	Mixtures
4.1.	Description of first aid measures
5.1.	Extinguishing media
6.3.	Methods and material for containment and cleaning up
7.1.	Precautions for safe handling
8.1.	Control parameters
8.2.	Exposure controls
9.1.	Information on basic physical and chemical properties
11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008

11.2.	Information on other hazards
12.1.	Toxicity
12.5.	Results of PBT and vPvB assessment
12.6.	Endocrine disrupting properties
13.1.	Waste treatment methods
14.3.	Transport hazard class(es)
16.1.	Indication of changes
16.2.	Abbreviations and acronyms
16.5.	List of relevant hazard statements and/or precautionary statements from sections 2 to 15

*
16.2. Abbreviations and acronyms

ACGIH	American Conference of Governmental Industrial Hygienists
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
ATE	Acute Toxicity Estimate
AVV	Waste Shipment Ordinance (DE)
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging
DIN	German Institute for Standardization / German Industrial Standard
DNEL	derived no-effect level
EAK	European Waste Catalogue
EC_{50}	Effective Concentration 50%
EG	European Community
EN	European Standard
ES	Exposure scenario
EU	European Union
EWC	European Waste Catalogue
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
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
Tox.	Toxicity
TRGS	Technische Regeln für Gefahrstoffe
UFI	Unique Formula Identifier
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]
The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

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

Hazard statements	
H300	Fatal if swallowed.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Supplemental hazard information	
EUH032	Contact with acids liberates very toxic gas.

16.6. Training advice
No data available

16.7. Additional information
No data available

* Data changed compared with the previous version.