

SAFETY DATA SHEET

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

Revision date: 10 Apr 2024

Print date: 10 Apr 2024

Version: 1.1

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anti-Varicella Zoster Virus (VZV) mAB IgM in human serum matrix - MAB104.001H

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

1.1. Product identifier

Trade name/designation:

anti-Varicella Zoster Virus (VZV) mAB IgM in human serum matrix - MAB104.001H

Article No.:

MAB104.001H

UFI:

91FY-2HWG-0V0U-VRD1

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
Skin corrosion/irritation (<i>Skin Irrit. 2</i>)	H315: Causes skin irritation.	
Respiratory or skin sensitisation (<i>Skin Sens. 1</i>)	H317: May cause an allergic skin reaction.	
Serious eye damage/eye irritation (<i>Eye Irrit. 2</i>)	H319: Causes serious eye irritation.	
Hazardous to the aquatic environment (<i>Aquatic Chronic 2</i>)	H411: Toxic to aquatic life with long lasting effects.	

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2.2. Label elements

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

Hazard pictograms:



GHS07

Exclamation mark



GHS09

Environment

Signal word: Warning

Hazard statements for health hazards

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.

Hazard statements for environmental hazards

H411	Toxic to aquatic life with long lasting effects.
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Supplemental hazard information: none

Precautionary statements Prevention

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.

Precautionary statements Response

P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313	If skin irritation occurs: Get medical advice/attention.
P337 + P313	If eye irritation persists: Get medical advice/attention.

2.3. Other hazards

No data available

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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.: 2682-20-4 EC No.: 220-239-6 Index No.: 613-326-00-9 REACH No.: 01-2120764690-50	ProClin 950 Acute Tox. 2 (H330), Acute Tox. 3 (H311, H301), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), Eye Dam. 1 (H318), Skin Corr. 1B (H314), Skin Sens. 1A (H317)    Danger EUH071 M-factor (acute): 10 M-factor (chronic): 1 Specific concentration limit (SCL) Skin Sens. 1A; H317: C ≥ 0.0015%	0 - ≤ 0.15 weight-%
CAS No.: 55965-84-9 EC No.: 911-418-6 Index No.: 613-167-00-5 REACH No.: 01-2120764691-48-XXXX	ProClin 300 Acute Tox. 2 (H330, H310), Acute Tox. 3 (H301), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), Eye Dam. 1 (H318), Skin Corr. 1C (H314), Skin Sens. 1A (H317)    Danger EUH071 M-factor (acute): 100 M-factor (chronic): 100 Specific concentration limit (SCL) Skin Corr. 1C; H314: C ≥ 0.6% Skin Irrit. 2; H315: 0.06% ≤ C < 0.6% Eye Dam. 1; H318: C ≥ 0.6% Eye Irrit. 2; H319: 0.06% ≤ C < 0.6% Skin Sens. 1A; H317: C ≥ 0.0015%	0 - ≤ 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.

In case of skin contact:

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

After eye contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: 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.

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

Skin corrosion/irritation. Allergic reactions. Serious eye damage/eye irritation.

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

Treat symptomatically.

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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.

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).

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.

Storage class (TRGS 510, Germany): 8A - Combustible corrosive substances

7.3. Specific end use(s)

No data available

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SECTION 8: Exposure controls/personal protection

* 8.1. Control parameters

No data available

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.

Respiratory protection:

Observe the wear time limits as specified by the manufacturer.

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	at °C	① Method ② Remark
pH	= 7.4	20 °C	
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

No data available

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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

ProClin 950 CAS No.: 2682-20-4 EC No.: 220-239-6
LD₅₀ oral: >2,000 mg/kg
ProClin 300 CAS No.: 55965-84-9 EC No.: 911-418-6
LD₅₀ oral: 66 mg/kg (Rat)
LD₅₀ dermal: 87.12 mg/kg (Rabbit) ECHA
LC₅₀ Acute inhalation toxicity (dust/mist): 0.171 mg/L (Rat)

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:

Causes skin irritation.

Serious eye damage/irritation:

Causes serious eye irritation.

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.

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

ProClin 950 CAS No.: 2682-20-4 EC No.: 220-239-6
LC ₅₀ : 4.77 mg/L 4 d (fish)
LC ₅₀ : 4.77 mg/L 4 d (fish, Oncorhynchus mykiss (Rainbow trout)) OECD Prüfrichtlinie 203
EC ₅₀ : 0.85 mg/L 2 d (crustaceans)
EC ₅₀ : 0.069 mg/L 4 d (shellfish)
EC ₅₀ : 41 mg/L (Activated sludge)
ProClin 300 CAS No.: 55965-84-9 EC No.: 911-418-6
LC ₅₀ : 0.16 mg/L 4 d (Oncorhynchus mykiss (Rainbow trout))
LC ₅₀ : 0.18 mg/L 2 d (Daphnia magna (Big water flea))
LC ₅₀ : 0.19 mg/L 4 d (fish)
EC ₅₀ : 4.8 mg/L (Activated sludge)
EC ₅₀ : 0.18 mg/L 2 d (crustaceans)
EC ₅₀ : 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))

Aquatic toxicity:

Toxic to aquatic life with long lasting effects.

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

* 12.5. Results of PBT and vPvB assessment

ProClin 950 CAS No.: 2682-20-4 EC No.: 220-239-6
Results of PBT and vPvB assessment: —
ProClin 300 CAS No.: 55965-84-9 EC No.: 911-418-6
Results of PBT and vPvB assessment: —

12.6. Endocrine disrupting properties

No data available

12.7. Other adverse effects

No data available

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 3082	UN 3082	UN 3082	UN 3082

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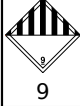
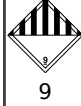
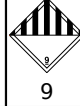




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Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.2. UN proper shipping name			
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
14.3. Transport hazard class(es)			
 9	 9	 9	 9
14.4. Packing group			
III	III	III	III
14.5. Environmental hazards			
		 MARINE POLLUTANT	
14.6. Special precautions for user			
Special Provisions: 274 335 375 601 Limited quantity (LQ): 5 L Excepted Quantities (EQ): E1 Hazard identification number (Kemler No.): 90 Classification code: M6 Tunnel restriction code: (-)	Special Provisions: 274 335 375 601 Limited quantity (LQ): 5 L Excepted Quantities (EQ): E1 Classification code: M6	Special Provisions: 274 335 969 Limited quantity (LQ): 5 L Excepted Quantities (EQ): E1 EmS-No.: F-A, S-F	Special Provisions: A97 A158 A197 A215 Limited quantity (LQ): Y964 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

15.1.1. EU legislation

Other regulations (EU):

Hazard categories:

- E2 Hazardous to the Aquatic Environment in Category Chronic 2

15.1.2. National regulations

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
3.2.	Mixtures
8.1.	Control parameters

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9.1.	Information on basic physical and chemical properties
11.1.	Information on hazard classes as defined in Regulation (EC) No 1272/2008
12.1.	Toxicity
12.5.	Results of PBT and vPvB assessment
15.1.	Safety, health and environmental regulations/legislation specific for the substance or mixture
16.1.	Indication of changes
16.5.	List of relevant hazard statements and/or precautionary statements from sections 2 to 15

16.2. Abbreviations and acronyms

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
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
NOEC	No Observed Effect Concentration
OECD	Organisation for Economic Cooperation and Development
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
Skin corrosion/irritation (<i>Skin Irrit. 2</i>)	H315: Causes skin irritation.	
Respiratory or skin sensitisation (<i>Skin Sens. 1</i>)	H317: May cause an allergic skin reaction.	
Serious eye damage/eye irritation (<i>Eye Irrit. 2</i>)	H319: Causes serious eye irritation.	
Hazardous to the aquatic environment (<i>Aquatic Chronic 2</i>)	H411: Toxic to aquatic life with long lasting effects.	

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

Hazard statements	
H301	Toxic if swallowed.
H310	Fatal in contact with skin.

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Hazard statements

H311	Toxic 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.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Supplemental hazard information

EUH071	Corrosive to the respiratory tract.
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16.6. Training advice

No data available

16.7. Additional information

No data available

* Data changed compared with the previous version.