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

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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

1.4. Emergency telephone number

No data available

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 (Skin Irrit. 2) | H315: Causes skin irritation. | |
| Respiratory or skin sensitisation (Skin Sens. 1) | H317: May cause an allergic skin reaction. | |
| Serious eye damage/eye irritation (Eye Irrit. 2) | H319: Causes serious eye irritation. | |
| Hazardous to the aquatic environment (Aquatic Chronic 2) | 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

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. |

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 | |
|-----------------------------------|--|
| | 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

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous ingredients / Hazardous impurities / Stabilisers:

| Product identifiers | Substance name | Concentration |
|--|---|------------------------|
| | Classification according to Regulation (EC) No 1272/2008 [CLP] | |
| 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 Index No.: 613-167-00-5 | 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)

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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 |
| рН | = 7.4 | 20 °C | |
| Melting point | not determined | | |
| Freezing point | not determined | | |
| Initial boiling point and boiling range | not determined | | |
| Decomposition temperature | not determined | | |
| Flash point | not determined | | |
| Evaporation rate | not determined | | |
| Auto-ignition temperature | not determined | | |
| Upper/lower flammability or explosive limits | not determined | | |
| Vapour pressure | not determined | | |
| Vapour density | not determined | | |
| Density | not determined | | |
| Relative density | not determined | | |
| Bulk density | not determined | | |
| Water solubility | not determined | | |
| Partition coefficient: n-octanol/water | not determined | | |
| Dynamic viscosity | not determined | | |
| Kinematic viscosity | not determined | | |

9.2. Other information

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

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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

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

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:

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11.2. Information on other hazards

No data available

SECTION 12: Ecological information

12.1. Toxicity

ProClin 950 CAS No.: 2682-20-4 EC No.: 220-239-6

LC₅₀: 4.77 mg/L 4 d (fish)

EC₅₀: 0.85 mg/L 2 d (crustaceans)

EC₅₀: 0.069 mg/L 4 d (shellfish)

EC₅₀: 41 mg/L (Activated sludge)

ProClin 300 CAS No.: 55965-84-9

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

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

EC₅₀: 4.8 mg/L (Activated sludge)

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

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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| Land transport (ADR/RID) | Inland waterway craft (ADN) | Sea transport (IMDG) | Air transport (ICAO-TI / IATA-DGR) |
|---|---|---|---|
| 14.2. UN proper ship | ping 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 haza | rd class(es) | | |
| | | | |
| 9 | 9 | 9 | 9 |
| 14.4. Packing group | | | |
| III | Ш | III | III |
| 14.5. Environmental | hazards | | |
| ¥2> | 1 | MARINE POLLUTANT | ¥2> |
| 14.6. Special precau | tions for user | | |
| Special Provisions: 274 335 375 601 Limited quantity (LQ): 5 L | Special Provisions: 274 335 375 601 Limited quantity (LQ): 5 L | Special Provisions: 274 335 969 Limited quantity (LQ): 5 L | Special Provisions: A97 A158 A197 A215 Limited quantity (LQ): Y964 |
| Excepted Quantities (EQ): E1 Hazard identification number (Kemler No.): | Excepted Quantities (EQ): E1 Classification code: M6 | Excepted Quantities (EQ): E1 EmS-No.: F-A, S-F | Excepted Quantities (EQ): E1 |
| 90 | | , 5. | |
| Classification code: | | | |
| Tunnel restriction code: (-) | | | |

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):

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances [Seveso-III-Directive], 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

No data available

16.2. Abbreviations and acronyms

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

16.5. Relevant R-, H- and EUH-phrases (Number and full text)

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

16.6. Training advice

No data available

16.7. Additional information