EPSTEIN-BARR VCA VIRCLIA® IgM MONOTEST

Safety Data Sheet

according to Regulation (EU) 2015/830

Revision date:19/11/2015

VIRCLIA® KIT includes several mixtures, which have all been evaluated for classification, according to Regulation (EC) No. 1272/2008 [CLP]

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

1.1. Product identifier

Product name: EPSTEIN-BARR VCA VIRCLIA® IgM MONOTEST

Product code: VCM028

Product form: Mixture

Trade name: VIRCLIA® KIT

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

1.2.1. Relevant identified uses

Use of the substance/mixture: In vitro Diagnostic Test

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

VIRCELL, S.L.
Parque Tecnológico de la Salud, Avicena 8
18016 Granada - Spain
T +34 958 441264 - F +34 958510712
customerservice@vircell.com

1.4. Emergency telephone number

Emergency number: 112 (24 hour service) – applicable to EU countries only

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

2.2. Label elements

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

No labelling required

2.3. Other hazards

Other hazards which do not result in classification: Reagents should be considered as potentially infectious and handled accordingly

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of breathing difficulties administer oxygen. If you feel unwell, seek medical attention

First-aid measures after skin contact: After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water and soap. If skin irritation occurs: Get medical advice/attention

First-aid measures after eye contact: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention if ill effect or irritation develops

First-aid measures after ingestion: If swallowed, rinse mouth with water (only if the person is conscious). Do not induce vomiting. Never give anything by mouth to an unconscious person. Consult a doctor/medical service if you feel unwell

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

Symptoms/injuries after skin contact: May cause moderate irritation

Symptoms/injuries after eye contact: May cause moderate irritation

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Water, carbon dioxide (CO2), dry chemical powder, foam

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Precautionary measures fire: Evacuate the personnel away from the fumes

Protective equipment for firefighters: Extra personal protection: complete protective clothing including self-contained breathing apparatus

Other information: Collect contaminated fire extinguishing water separately. This must not be discharged into drains

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures: Alert emergency personnel

6.1.2. For emergency responders

Protective equipment: Wear suitable protective clothing, gloves and eye/face protection. Avoid breathing dust/fume/gas/mist/vapours/spray

Emergency procedures: Evacuate unnecessary personnel

6.2. Environmental precautions

Avoid release to the environment

6.3. Methods and material for containment and cleaning up

For containment: Stop leak if safe to do so

Methods for cleaning up: Ventilate affected area. Wear personal protection equipment. Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Wash with plenty of soap and water. Consult the appropriate authorities about waste disposal

Other information: Do not allow uncontrolled discharge of product into the environment

6.4. Reference to other sections

For disposal of residues refer to section 13: Disposal considerations. For further information refer to section 8: "Exposure controls/personal protection"

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling: Avoid contact with skin and eyes

Hygiene measures: Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Keep container tightly closed. Store in a well-ventilated place. Keep cool

Heat and ignition sources: Keep away from open flames, hot surfaces and sources of ignition

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls: Provide adequate ventilation

Personal protective equipment: Gloves. Protective goggles. Protective clothing

Hand protection: Wear suitable gloves tested to EN374

Eye protection: Chemical goggles or safety glasses

Skin and body protection: Use chemically protective clothing. Lab coat

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Includes several mixtures

Colour: No data available

Odour: No data available

Odour threshold: No data available

pH: No data available

Relative evaporation rate (butyl acetate=1):	No data available
Melting point:	No data available
Freezing point:	No data available
Boiling point:	No data available
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Flammability (solid, gas):	No data available
Vapour pressure:	No data available
Relative vapour density at 20 °C:	No data available
Relative density:	No data available
Solubility:	No data available
Log Pow:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Explosive properties:	No data available
Oxidising properties:	No data available
Explosive limits:	No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

No polymerization

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity:	Not classified
Skin corrosion/irritation:	Not classified
Serious eye damage/irritation:	Not classified
Respiratory or skin sensitisation:	Not classified
Germ cell mutagenicity:	Not classified
Carcinogenicity:	Not classified
Reproductive toxicity:	Not classified
Specific target organ toxicity (single exposure):	Not classified
Specific target organ toxicity (repeated exposure):	Not classified
Aspiration hazard:	Not classified

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods: Consult the appropriate local waste disposal expert about waste disposal

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR):	Not applicable
Proper Shipping Name (IMDG):	Not applicable
Proper Shipping Name (IATA):	Not applicable
Proper Shipping Name (ADN):	Not applicable
Proper Shipping Name (RID):	Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR):	Not applicable

IMDG

Transport hazard class(es) (IMDG):	Not applicable

IATA

Transport hazard class(es) (IATA):	Not applicable

ADN

Transport hazard class(es) (ADN):	Not applicable

RID

Transport hazard class(es) (RID):	Not applicable

14.4. Packing group

Packing group (ADR):	Not applicable
Packing group (IMDG):	Not applicable
Packing group (IATA):	Not applicable
Packing group (ADN):	Not applicable
Packing group (RID):	Not applicable

14.5. Environmental hazards

Dangerous for the environment:	No
Marine pollutant:	No
Other information:	No supplementary information available

14.6. Special precautions for user

- Overland transport
No data available

- Transport by sea
No data available

- Air transport
No data available

- Inland waterway transport
No data available

- Rail transport
No data available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XVI substances

15.1.2. National regulations

Germany

VwVwS Annex reference:	Water hazard class (WGK) 1, low hazard to waters (Classification according to VwVwS, Annex 4)
12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV	Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rai
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic
	CAS - Chemical Abstracts Service
	CSR - Chemical Safety Report

Other information: This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product. It is the user's responsibility to take the mentioned precautionary measures and to ensure that this information is complete and sufficient for the use of this product

SDS EU (REACH Annex II)

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