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: RICKETTSIA CONORII VIRCLIA® IgM MONOTEST

Product code: VCM082

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 measure	es
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	a offects which assure and delayed

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

Symptoms/injuries after skin contact:	May cause moderate irritation
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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



Safety Data Sheet according to Regulation (EU) 2015/830 **SECTION 5: Firefighting measures** 5.1. Extinguishing media Water, carbon dioxide (CO2), dry chemical powder, foam Suitable extinguishing media: 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

8.2. Exposure controls

No additional information available

Appropriate engineering controls: Personal protective equipment:	Provide adequate ventilation 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 ch	emical properties
Physical state:	Includes several mixtures
Colour:	No data available
Odour:	No data available
Odour threshold:	No data available
pH:	No data available

Safety Data Sheet

according to Regulation (EU) 2015/830

ľ	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

Safety Data Sheet

according to Regulation (EU) 2015/830

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	
	priate local waste disposal expert about waste disposal
SECTION 14: Transport information In accordance with ADR / RID / IMDG / IATA /	
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): Proper Shipping Name (RID):	Not applicable
	Not applicable
14.3. Transport hazard class(es)	
ADR	
Transport hazard class(es) (ADR): IMDG	Not applicable
Transport hazard class(es) (IMDG): IATA	Not applicable
Transport hazard class(es) (IATA): ADN	Not applicable
Transport hazard class(es) (ADN): RID	Not applicable
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	
19/11/2015	EN (English) 4/

Safety Data Sheet

according to Regulation (EU) 2015/830

- 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. BlmSchV (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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