

BORDETELLA PERTUSSIS TOXIN VIRCLIA® IgG MONOTEST

VIRCLIA® BORDETELLA PERTUSSIS TOXIN IgG MONODOSE

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Edition: 4. Date: 09/02/2023



This SDS refers exclusively to: VIRCLIA® BORDETELLA PERTUSSIS TOXIN IgG MONODOSE.

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

1.1. Product identifier

Product form	: Mixture
Product name	: BORDETELLA PERTUSSIS TOXIN VIRCLIA® IgG MONOTEST
Trade name	: VIRCLIA® KIT (VIRCLIA® BORDETELLA PERTUSSIS TOXIN IgG MONODOSE)
Product code	: VCM092

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

1.2.1. Relevant identified uses

Industrial/Professional use specifications	: For professional use only.
Use of the substance/mixture	: <i>In Vitro</i> Diagnostic use.

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 +34 958-44 12 64 - F +34 958-51 07 12
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]

Skin sensitisation, category 1 H317

Full text of H statements : see section 16.

Adverse physicochemical, human health and environmental effects

No additional information available.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07: Health hazard/Hazardous to the ozone layer.

Signal word (CLP) :

Warning.

Hazardous ingredients :

2-Methyl-2H-isothiazol-3-one.

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) :

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 - If on skin: Wash with plenty of water.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

2.3. Other hazards

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

The mixture does not contain PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	0.01 – 0.05	Acute Tox. 3 (Oral), H301 (ATE= 100 mg/kg bodyweight) Acute Tox. 3 (Dermal), H311 (ATE = 300 mg/kg bodyweight) Acute Tox. 2 (Inhalation), H330 (ATE = 0.05 mg/l/4h) Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1)

Specific concentration limits:

Name	Product identifier	Specific concentration limits
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	(0.0015 =<C < 100) Skin Sens. 1A, H317

Full text of H-statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell. If medical advice is needed, have product container or label at hand.
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 advice.
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/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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	: Water, carbon dioxide (CO ₂), dry chemical powder, foam.
Unsuitable extinguishing media	: No data available.

5.2. Special hazards arising from the substance or mixture

Fire hazard:	: No data available.
Explosion hazard:	: No data available.
Hazardous decomposition products in case of fire:	: No data 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. Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire.

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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. Ensure adequate ventilation, especially in confined areas.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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 (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. See Section 1 for emergency contact information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes. Provide adequate ventilation. Avoid formation of vapours. Do not breathe gas, fumes, vapour or spray.

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.

Storage temperature : 2 - 8 °C.

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

Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

In Vitro Diagnostic use. Use the product in compliance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Austria - Occupational Exposure Limits	
Local name	2-Methyl-(2H)-isothiazol-3-on
MAK (mg/m ³)	0.05 mg/m ³ 2-Methyl-(2H)-isothiazol-3-on
Remark (AT)	Sh,H
OEL chemical category (AT)	Skin sensitizer
Regulatory reference	BGBl. II Nr. 186/2015
Germany - Occupational Exposure Limits (TRGS 900)	
Local name	2-Methyl-(2H)-isothiazol-3-on
Occupational exposure limit value (mg/m ³)	0.2 mg/m ³
Switzerland - Occupational Exposure Limits	
Local name	2-méthylisothiazol-3(2H)-one
MAK (mg/m ³)	0.2 mg/m ³ (i) / (e)
KZGW (mg/m ³)	0.4 mg/m ³ (i) / (e)
Critical toxicity	VRS, Skin, Eye / OAW
Notation	S, SS _c / S, SS _c
Regulatory reference	www.suva.ch, 01.07.2019

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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 EN 374. FKM (fluoro rubber). Breakthrough time: < 1 h. Layer thickness: 0.4 mm.

Eye protection:

Chemical goggles or safety glasses. EN 166.

Skin and body protection:

Use chemically protective clothing. Lab coat.

Respiratory protection:

Not required for normal conditions of use.

Personal protective equipment symbol(s):



Environmental exposure controls:

Do not allow into drains or water courses.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid.
Colour	: Not determined.
Odour	: Not determined.
Odour threshold	: Not determined.
pH	: Not determined.
Relative evaporation rate (butylacetate=1)	: Not determined.
Melting point	: Not determined.
Freezing point	: Not determined.
Boiling point	: Not determined.
Flash point	: Not determined.
Auto-ignition temperature	: Not determined.
Decomposition temperature	: Not determined.
Flammability (solid, gas)	: Not determined.
Vapour pressure	: Not determined.
Relative vapour density at 20 °C	: Not determined.
Relative density	: Not determined.
Solubility	: Completely soluble.
Log Pow	: Not determined.
Viscosity, kinematic	: Not determined.
Viscosity, dynamic	: Not determined.
Explosive properties	: Not explosive.
Oxidising properties	: Not oxidising.
Explosive limits	: Not determined.
Particle characteristics	: Not applicable.

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available.

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9.2.2. Other safety characteristics

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. No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

No additional information available.

10.5. Incompatible materials

Strong oxidising agents. Reducing agents. Amines. Mercaptan.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂). Nitrogen oxides. Sulphur oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified.
Acute toxicity (dermal)	: Not classified.
Acute toxicity (inhalation)	: Not classified.
Skin corrosion/irritation	: Not classified.
Serious eye damage/irritation	: Not classified.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified.
Carcinogenicity	: Not classified.
Reproductive toxicity	: Not classified.
STOT-single exposure	: Not classified.
STOT-repeated exposure	: Not classified.
Aspiration hazard	: Not classified.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified.

Hazardous to the aquatic environment, long-term (chronic) : Not classified.

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

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12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

12.7. 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.

Product/Packaging disposal recommendations : Handle uncleaned empty containers as full ones.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

No additional information available.

14.6. Special precautions for user

Overland transport

Not regulated.

Transport by sea

Not regulated.

Air transport

Not regulated.

Inland waterway transport

Not regulated.

Rail transport

Not regulated.

14.7. Maritime transport in bulk according to IMO instruments

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 XIV substances.

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

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15.1.2. National regulations

Germany

Reference to AwSV : Water hazard class (WGK) 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance).

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed.

SZW-lijst van mutagene stoffen : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed.

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product.

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 Rail
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	CAS (Chemical Abstracts Service) number
CSR	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 mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product. This document shall be only used and considered as a guideline requiring appropriate and professional chemical handling of this product with caution or under qualified supervision. This product is not intended for purposes alien to those displayed in section 1, unless being informed adequately by written instructions on handling procedures considering this material. This product shall be used in compliance with the Good Laboratory Practice. All potential dangers involved in the interactions of the described product with additional materials and chemicals are not indicated in this form. The user is the solely responsible agent regarding the product's suitability for the intended use, the product's safe use as well as its safe disposal. No warranty or representation, either explicit or implicit, of merchantability, suitable for a specific purpose or of any other nature is made hereunder with respect to the information set forth or to product which the information refers.

Full text of H- and EUH-statements:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1

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Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Skin Corr. 1B	Skin corrosion/irritation, Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
Skin Sens. 1A	Skin sensitisation, category 1A	
H301	Toxic if swallowed.	
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.	
Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1	H317	Calculation method

SDS EU (REACH Annex II)

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.

CHLAMYDOPHILA PNEUMONIAE VIRCLIA® IgG MONOTEST

VIRCLIA® CHLAMYDOPHILA PNEUMONIAE IgG MONODOSE

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Edition: 4. Date: 09/02/2023



This SDS refers exclusively to: VIRCLIA® CHLAMYDOPHILA PNEUMONIAE IgG MONODOSE.

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

1.1. Product identifier

Product form : Mixture
Product name : **CHLAMYDOPHILA PNEUMONIAE VIRCLIA® IgG MONOTEST**
Trade name : **VIRCLIA® KIT** (VIRCLIA® CHLAMYDOPHILA PNEUMONIAE IgG MONODOSE)
Product code : **VCM017**

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

1.2.1. Relevant identified uses

Industrial/Professional use specifications : For professional use only.
Use of the substance/mixture : *In Vitro* Diagnostic use.

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 +34 958-44 12 64 - F +34 958-51 07 12
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]

Skin sensitisation, category 1 H317

Full text of H statements : see section 16.

Adverse physicochemical, human health and environmental effects

No additional information available.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07: Health hazard/Hazardous to the ozone layer.

Signal word (CLP) :

Warning.

Hazardous ingredients :

2-Methyl-2H-isothiazol-3-one.

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) :

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 - Contaminated work clothing should not be allowed out of the workplace.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 - If on skin: Wash with plenty of water.

P321 - Specific treatment (see supplemental first aid instruction on this label).

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

2.3. Other hazards

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

The mixture does not contain PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	0.01 – 0.05	Acute Tox. 3 (Oral), H301 (ATE= 100 mg/kg bodyweight) Acute Tox. 3 (Dermal), H311 (ATE = 300 mg/kg bodyweight) Acute Tox. 2 (Inhalation), H330 (ATE = 0.05 mg/l/4h) Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1)

Specific concentration limits:

Name	Product identifier	Specific concentration limits
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	(0.0015 =<C < 100) Skin Sens. 1A, H317

Full text of H-statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell. If medical advice is needed, have product container or label at hand.
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 advice.
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/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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	: Water, carbon dioxide (CO ₂), dry chemical powder, foam.
Unsuitable extinguishing media	: No data available.

5.2. Special hazards arising from the substance or mixture

Fire hazard:	: No data available.
Explosion hazard:	: No data available.
Hazardous decomposition products in case of fire:	: No data 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. Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire.

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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. Ensure adequate ventilation, especially in confined areas.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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 (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. See Section 1 for emergency contact information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes. Provide adequate ventilation. Avoid formation of vapours. Do not breathe gas, fumes, vapour or spray.

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.

Storage temperature : 2 - 8 °C.

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

Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

In Vitro Diagnostic use. Use the product in compliance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Austria - Occupational Exposure Limits	
Local name	2-Methyl-(2H)-isothiazol-3-on
MAK (mg/m ³)	0.05 mg/m ³ 2-Methyl-(2H)-isothiazol-3-on
Remark (AT)	Sh,H
OEL chemical category (AT)	Skin sensitizer
Regulatory reference	BGBl. II Nr. 186/2015
Germany - Occupational Exposure Limits (TRGS 900)	
Local name	2-Methyl-(2H)-isothiazol-3-on
Occupational exposure limit value (mg/m ³)	0.2 mg/m ³
Switzerland - Occupational Exposure Limits	
Local name	2-méthylisothiazol-3(2H)-one
MAK (mg/m ³)	0.2 mg/m ³ (i) / (e)
KZGW (mg/m ³)	0.4 mg/m ³ (i) / (e)
Critical toxicity	VRS, Skin, Eye / OAW
Notation	S, SS _c / S, SS _c
Regulatory reference	www.suva.ch, 01.07.2019

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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 EN 374. FKM (fluoro rubber). Breakthrough time: < 1 h. Layer thickness: 0.4 mm.

Eye protection:

Chemical goggles or safety glasses. EN 166.

Skin and body protection:

Use chemically protective clothing. Lab coat.

Respiratory protection:

Not required for normal conditions of use.

Personal protective equipment symbol(s):



Environmental exposure controls:

Do not allow into drains or water courses.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid.
Colour	: Not determined.
Odour	: Not determined.
Odour threshold	: Not determined.
pH	: Not determined.
Relative evaporation rate (butylacetate=1)	: Not determined.
Melting point	: Not determined.
Freezing point	: Not determined.
Boiling point	: Not determined.
Flash point	: Not determined.
Auto-ignition temperature	: Not determined.
Decomposition temperature	: Not determined.
Flammability (solid, gas)	: Not determined.
Vapour pressure	: Not determined.
Relative vapour density at 20 °C	: Not determined.
Relative density	: Not determined.
Solubility	: Completely soluble.
Log Pow	: Not determined.
Viscosity, kinematic	: Not determined.
Viscosity, dynamic	: Not determined.
Explosive properties	: Not explosive.
Oxidising properties	: Not oxidising.
Explosive limits	: Not determined.
Particle characteristics	: Not applicable.

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available.

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9.2.2. Other safety characteristics

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. No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

No additional information available.

10.5. Incompatible materials

Strong oxidising agents. Reducing agents. Amines. Mercaptan.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂). Nitrogen oxides. Sulphur oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified.
Acute toxicity (dermal)	: Not classified.
Acute toxicity (inhalation)	: Not classified.
Skin corrosion/irritation	: Not classified.
Serious eye damage/irritation	: Not classified.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified.
Carcinogenicity	: Not classified.
Reproductive toxicity	: Not classified.
STOT-single exposure	: Not classified.
STOT-repeated exposure	: Not classified.
Aspiration hazard	: Not classified.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified.

Hazardous to the aquatic environment, long-term (chronic) : Not classified.

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

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12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

12.7. 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.

Product/Packaging disposal recommendations : Handle uncleaned empty containers as full ones.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

No additional information available.

14.6. Special precautions for user

Overland transport

Not regulated.

Transport by sea

Not regulated.

Air transport

Not regulated.

Inland waterway transport

Not regulated.

Rail transport

Not regulated.

14.7. Maritime transport in bulk according to IMO instruments

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 XIV substances.

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

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15.1.2. National regulations

Germany

Reference to AwSV : Water hazard class (WGK) 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance).

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed.

SZW-lijst van mutagene stoffen : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed.

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product.

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 Rail
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	CAS (Chemical Abstracts Service) number
CSR	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 mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product. This document shall be only used and considered as a guideline requiring appropriate and professional chemical handling of this product with caution or under qualified supervision. This product is not intended for purposes alien to those displayed in section 1, unless being informed adequately by written instructions on handling procedures considering this material. This product shall be used in compliance with the Good Laboratory Practice. All potential dangers involved in the interactions of the described product with additional materials and chemicals are not indicated in this form. The user is the solely responsible agent regarding the product's suitability for the intended use, the product's safe use as well as its safe disposal. No warranty or representation, either explicit or implicit, of merchantability, suitable for a specific purpose or of any other nature is made hereunder with respect to the information set forth or to product which the information refers.

Full text of H- and EUH-statements:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1

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Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Skin Corr. 1B	Skin corrosion/irritation, Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
Skin Sens. 1A	Skin sensitisation, category 1A	
H301	Toxic if swallowed.	
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.	
Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1	H317	Calculation method

SDS EU (REACH Annex II)

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.

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Edition: 4. Date: 09/02/2023



This SDS refers exclusively to: VIRCLIA® CHLAMYDOPHILA PNEUMONIAE IgM MONODOSE.

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

1.1. Product identifier

Product form : Mixture
Product name : **CHLAMYDOPHILA PNEUMONIAE VIRCLIA® IgM MONOTEST**
Trade name : **VIRCLIA® KIT** (VIRCLIA® CHLAMYDOPHILA PNEUMONIAE IgM MONODOSE)
Product code : **VCM018**

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

1.2.1. Relevant identified uses

Industrial/Professional use specifications : For professional use only.
Use of the substance/mixture : *In Vitro* Diagnostic use.

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 +34 958-44 12 64 - F +34 958-51 07 12
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]

Skin sensitisation, category 1 H317

Full text of H statements : see section 16.

Adverse physicochemical, human health and environmental effects

No additional information available.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07: Health hazard/Hazardous to the ozone layer.

Signal word (CLP) :

Warning.

Hazardous ingredients :

2-Methyl-2H-isothiazol-3-one.

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) :

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 - Contaminated work clothing should not be allowed out of the workplace.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 - If on skin: Wash with plenty of water.

P321 - Specific treatment (see supplemental first aid instruction on this label).

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

2.3. Other hazards

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

The mixture does not contain PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	0.01 – 0.05	Acute Tox. 3 (Oral), H301 (ATE= 100 mg/kg bodyweight) Acute Tox. 3 (Dermal), H311 (ATE = 300 mg/kg bodyweight) Acute Tox. 2 (Inhalation), H330 (ATE = 0.05 mg/l/4h) Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1)

Specific concentration limits:

Name	Product identifier	Specific concentration limits
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	(0.0015 =<C < 100) Skin Sens. 1A, H317

Full text of H-statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell. If medical advice is needed, have product container or label at hand.
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 advice.
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/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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	: Water, carbon dioxide (CO ₂), dry chemical powder, foam.
Unsuitable extinguishing media	: No data available.

5.2. Special hazards arising from the substance or mixture

Fire hazard:	: No data available.
Explosion hazard:	: No data available.
Hazardous decomposition products in case of fire:	: No data 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. Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire.

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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. Ensure adequate ventilation, especially in confined areas.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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 (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. See Section 1 for emergency contact information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes. Provide adequate ventilation. Avoid formation of vapours. Do not breathe gas, fumes, vapour or spray.

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.

Storage temperature : 2 - 8 °C.

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

Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

In Vitro Diagnostic use. Use the product in compliance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Austria - Occupational Exposure Limits	
Local name	2-Methyl-(2H)-isothiazol-3-on
MAK (mg/m ³)	0.05 mg/m ³ 2-Methyl-(2H)-isothiazol-3-on
Remark (AT)	Sh,H
OEL chemical category (AT)	Skin sensitizer
Regulatory reference	BGBl. II Nr. 186/2015
Germany - Occupational Exposure Limits (TRGS 900)	
Local name	2-Methyl-(2H)-isothiazol-3-on
Occupational exposure limit value (mg/m ³)	0.2 mg/m ³
Switzerland - Occupational Exposure Limits	
Local name	2-méthylisothiazol-3(2H)-one
MAK (mg/m ³)	0.2 mg/m ³ (i) / (e)
KZGW (mg/m ³)	0.4 mg/m ³ (i) / (e)
Critical toxicity	VRS, Skin, Eye / OAW
Notation	S, SS _c / S, SS _c
Regulatory reference	www.suva.ch, 01.07.2019

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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 EN 374. FKM (fluoro rubber). Breakthrough time: < 1 h. Layer thickness: 0.4 mm.

Eye protection:

Chemical goggles or safety glasses. EN 166.

Skin and body protection:

Use chemically protective clothing. Lab coat.

Respiratory protection:

Not required for normal conditions of use.

Personal protective equipment symbol(s):



Environmental exposure controls:

Do not allow into drains or water courses.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid.
Colour	: Not determined.
Odour	: Not determined.
Odour threshold	: Not determined.
pH	: Not determined.
Relative evaporation rate (butylacetate=1)	: Not determined.
Melting point	: Not determined.
Freezing point	: Not determined.
Boiling point	: Not determined.
Flash point	: Not determined.
Auto-ignition temperature	: Not determined.
Decomposition temperature	: Not determined.
Flammability (solid, gas)	: Not determined.
Vapour pressure	: Not determined.
Relative vapour density at 20 °C	: Not determined.
Relative density	: Not determined.
Solubility	: Completely soluble.
Log Pow	: Not determined.
Viscosity, kinematic	: Not determined.
Viscosity, dynamic	: Not determined.
Explosive properties	: Not explosive.
Oxidising properties	: Not oxidising.
Explosive limits	: Not determined.
Particle characteristics	: Not applicable.

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available.

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9.2.2. Other safety characteristics

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. No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

No additional information available.

10.5. Incompatible materials

Strong oxidising agents. Reducing agents. Amines. Mercaptan.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂). Nitrogen oxides. Sulphur oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified.
Acute toxicity (dermal)	: Not classified.
Acute toxicity (inhalation)	: Not classified.
Skin corrosion/irritation	: Not classified.
Serious eye damage/irritation	: Not classified.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified.
Carcinogenicity	: Not classified.
Reproductive toxicity	: Not classified.
STOT-single exposure	: Not classified.
STOT-repeated exposure	: Not classified.
Aspiration hazard	: Not classified.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified.

Hazardous to the aquatic environment, long-term (chronic) : Not classified.

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

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12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

12.7. 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.

Product/Packaging disposal recommendations : Handle uncleaned empty containers as full ones.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

No additional information available.

14.6. Special precautions for user

Overland transport

Not regulated.

Transport by sea

Not regulated.

Air transport

Not regulated.

Inland waterway transport

Not regulated.

Rail transport

Not regulated.

14.7. Maritime transport in bulk according to IMO instruments

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 XIV substances.

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

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15.1.2. National regulations

Germany

Reference to AwSV : Water hazard class (WGK) 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance).

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed.

SZW-lijst van mutagene stoffen : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed.

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product.

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 Rail
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	CAS (Chemical Abstracts Service) number
CSR	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 mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product. This document shall be only used and considered as a guideline requiring appropriate and professional chemical handling of this product with caution or under qualified supervision. This product is not intended for purposes alien to those displayed in section 1, unless being informed adequately by written instructions on handling procedures considering this material. This product shall be used in compliance with the Good Laboratory Practice. All potential dangers involved in the interactions of the described product with additional materials and chemicals are not indicated in this form. The user is the solely responsible agent regarding the product's suitability for the intended use, the product's safe use as well as its safe disposal. No warranty or representation, either explicit or implicit, of merchantability, suitable for a specific purpose or of any other nature is made hereunder with respect to the information set forth or to product which the information refers.

Full text of H- and EUH-statements:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1

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Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Skin Corr. 1B	Skin corrosion/irritation, Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
Skin Sens. 1A	Skin sensitisation, category 1A	
H301	Toxic if swallowed.	
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.	
Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1	H317	Calculation method

SDS EU (REACH Annex II)

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.

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Edition: 4. Date: 09/02/2023



This SDS refers exclusively to: VIRCLIA® HERPES SIMPLEX 1+2 IgG MONODOSE.

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

1.1. Product identifier

Product form : Mixture
Product name : **HERPES SIMPLEX 1+2 VIRCLIA® IgG MONOTEST**
Trade name : **VIRCLIA® KIT** (VIRCLIA® HERPES SIMPLEX 1+2 IgG MONODOSE)
Product code : **VCM034**

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

1.2.1. Relevant identified uses

Industrial/Professional use specifications : For professional use only.
Use of the substance/mixture : *In Vitro* Diagnostic use.

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 +34 958-44 12 64 - F +34 958-51 07 12
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]

Skin sensitisation, category 1 H317

Full text of H statements : see section 16.

Adverse physicochemical, human health and environmental effects

No additional information available.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07: Health hazard/Hazardous to the ozone layer.

Signal word (CLP) :

Warning.

Hazardous ingredients :

2-Methyl-2H-isothiazol-3-one.

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) :

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 - If on skin: Wash with plenty of water.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

2.3. Other hazards

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

The mixture does not contain PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	0.01 – 0.05	Acute Tox. 3 (Oral), H301 (ATE= 100 mg/kg bodyweight) Acute Tox. 3 (Dermal), H311 (ATE = 300 mg/kg bodyweight) Acute Tox. 2 (Inhalation), H330 (ATE = 0.05 mg/l/4h) Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1)

Specific concentration limits:

Name	Product identifier	Specific concentration limits
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	(0.0015 =<C < 100) Skin Sens. 1A, H317

Full text of H-statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell. If medical advice is needed, have product container or label at hand.
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 advice.
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/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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	: Water, carbon dioxide (CO ₂), dry chemical powder, foam.
Unsuitable extinguishing media	: No data available.

5.2. Special hazards arising from the substance or mixture

Fire hazard:	: No data available.
Explosion hazard:	: No data available.
Hazardous decomposition products in case of fire:	: No data 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. Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire.

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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. Ensure adequate ventilation, especially in confined areas.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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 (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. See Section 1 for emergency contact information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes. Provide adequate ventilation. Avoid formation of vapours. Do not breathe gas, fumes, vapour or spray.

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.

Storage temperature : 2 - 8 °C.

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

Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

In Vitro Diagnostic use. Use the product in compliance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Austria - Occupational Exposure Limits	
Local name	2-Methyl-(2H)-isothiazol-3-on
MAK (mg/m ³)	0.05 mg/m ³ 2-Methyl-(2H)-isothiazol-3-on
Remark (AT)	Sh,H
OEL chemical category (AT)	Skin sensitizer
Regulatory reference	BGBl. II Nr. 186/2015
Germany - Occupational Exposure Limits (TRGS 900)	
Local name	2-Methyl-(2H)-isothiazol-3-on
Occupational exposure limit value (mg/m ³)	0.2 mg/m ³
Switzerland - Occupational Exposure Limits	
Local name	2-méthylisothiazol-3(2H)-one
MAK (mg/m ³)	0.2 mg/m ³ (i) / (e)
KZGW (mg/m ³)	0.4 mg/m ³ (i) / (e)
Critical toxicity	VRS, Skin, Eye / OAW
Notation	S, SS _c / S, SS _c
Regulatory reference	www.suva.ch, 01.07.2019

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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 EN 374. FKM (fluoro rubber). Breakthrough time: < 1 h. Layer thickness: 0.4 mm.

Eye protection:

Chemical goggles or safety glasses. EN 166.

Skin and body protection:

Use chemically protective clothing. Lab coat.

Respiratory protection:

Not required for normal conditions of use.

Personal protective equipment symbol(s):



Environmental exposure controls:

Do not allow into drains or water courses.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid.
Colour	: Not determined.
Odour	: Not determined.
Odour threshold	: Not determined.
pH	: Not determined.
Relative evaporation rate (butylacetate=1)	: Not determined.
Melting point	: Not determined.
Freezing point	: Not determined.
Boiling point	: Not determined.
Flash point	: Not determined.
Auto-ignition temperature	: Not determined.
Decomposition temperature	: Not determined.
Flammability (solid, gas)	: Not determined.
Vapour pressure	: Not determined.
Relative vapour density at 20 °C	: Not determined.
Relative density	: Not determined.
Solubility	: Completely soluble.
Log Pow	: Not determined.
Viscosity, kinematic	: Not determined.
Viscosity, dynamic	: Not determined.
Explosive properties	: Not explosive.
Oxidising properties	: Not oxidising.
Explosive limits	: Not determined.
Particle characteristics	: Not applicable.

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available.

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9.2.2. Other safety characteristics

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. No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

No additional information available.

10.5. Incompatible materials

Strong oxidising agents. Reducing agents. Amines. Mercaptan.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂). Nitrogen oxides. Sulphur oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified.
Acute toxicity (dermal)	: Not classified.
Acute toxicity (inhalation)	: Not classified.
Skin corrosion/irritation	: Not classified.
Serious eye damage/irritation	: Not classified.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified.
Carcinogenicity	: Not classified.
Reproductive toxicity	: Not classified.
STOT-single exposure	: Not classified.
STOT-repeated exposure	: Not classified.
Aspiration hazard	: Not classified.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified.

Hazardous to the aquatic environment, long-term (chronic) : Not classified.

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

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12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

12.7. 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.

Product/Packaging disposal recommendations : Handle uncleaned empty containers as full ones.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

No additional information available.

14.6. Special precautions for user

Overland transport

Not regulated.

Transport by sea

Not regulated.

Air transport

Not regulated.

Inland waterway transport

Not regulated.

Rail transport

Not regulated.

14.7. Maritime transport in bulk according to IMO instruments

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 XIV substances.

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

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15.1.2. National regulations

Germany

Reference to AwSV : Water hazard class (WGK) 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance).

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed.

SZW-lijst van mutagene stoffen : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed.

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product.

15.2. Chemical safety assessment

No additional information available.

SECTION 16: Other information

Abbreviations and acronyms:

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RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
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	CAS (Chemical Abstracts Service) number
CSR	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 mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product. This document shall be only used and considered as a guideline requiring appropriate and professional chemical handling of this product with caution or under qualified supervision. This product is not intended for purposes alien to those displayed in section 1, unless being informed adequately by written instructions on handling procedures considering this material. This product shall be used in compliance with the Good Laboratory Practice. All potential dangers involved in the interactions of the described product with additional materials and chemicals are not indicated in this form. The user is the solely responsible agent regarding the product's suitability for the intended use, the product's safe use as well as its safe disposal. No warranty or representation, either explicit or implicit, of merchantability, suitable for a specific purpose or of any other nature is made hereunder with respect to the information set forth or to product which the information refers.

Full text of H- and EUH-statements:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1

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Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Skin Corr. 1B	Skin corrosion/irritation, Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
Skin Sens. 1A	Skin sensitisation, category 1A	
H301	Toxic if swallowed.	
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.	
Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1	H317	Calculation method

SDS EU (REACH Annex II)

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.

HERPES SIMPLEX 1+2 VIRCLIA® IgM MONOTEST

VIRCLIA® HERPES SIMPLEX 1+2 IgM MONODOSE

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Edition: 4. Date: 09/02/2023



This SDS refers exclusively to: VIRCLIA® HERPES SIMPLEX 1+2 IgM MONODOSE.

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

1.1. Product identifier

Product form : Mixture
Product name : **HERPES SIMPLEX 1+2 VIRCLIA® IgM MONOTEST**
Trade name : **VIRCLIA® KIT** (VIRCLIA® HERPES SIMPLEX 1+2 IgM MONODOSE)
Product code : **VCM036**

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

1.2.1. Relevant identified uses

Industrial/Professional use specifications : For professional use only.
Use of the substance/mixture : *In Vitro* Diagnostic use.

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 +34 958-44 12 64 - F +34 958-51 07 12
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]

Skin sensitisation, category 1 H317

Full text of H statements : see section 16.

Adverse physicochemical, human health and environmental effects

No additional information available.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07: Health hazard/Hazardous to the ozone layer.

Signal word (CLP) :

Warning.

Hazardous ingredients :

2-Methyl-2H-isothiazol-3-one.

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) :

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 - Contaminated work clothing should not be allowed out of the workplace.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 - If on skin: Wash with plenty of water.

P321 - Specific treatment (see supplemental first aid instruction on this label).

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

2.3. Other hazards

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

The mixture does not contain PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	0.01 – 0.05	Acute Tox. 3 (Oral), H301 (ATE= 100 mg/kg bodyweight) Acute Tox. 3 (Dermal), H311 (ATE = 300 mg/kg bodyweight) Acute Tox. 2 (Inhalation), H330 (ATE = 0.05 mg/l/4h) Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1)

Specific concentration limits:

Name	Product identifier	Specific concentration limits
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	(0.0015 =<C < 100) Skin Sens. 1A, H317

Full text of H-statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell. If medical advice is needed, have product container or label at hand.
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 advice.
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/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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	: Water, carbon dioxide (CO ₂), dry chemical powder, foam.
Unsuitable extinguishing media	: No data available.

5.2. Special hazards arising from the substance or mixture

Fire hazard:	: No data available.
Explosion hazard:	: No data available.
Hazardous decomposition products in case of fire:	: No data 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. Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire.

HERPES SIMPLEX 1+2 VIRCLIA® IgM MONOTEST

VIRCLIA® HERPES SIMPLEX 1+2 IgM MONODOSE

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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. Ensure adequate ventilation, especially in confined areas.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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 (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. See Section 1 for emergency contact information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes. Provide adequate ventilation. Avoid formation of vapours. Do not breathe gas, fumes, vapour or spray.

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.

Storage temperature : 2 - 8 °C.

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

Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

In Vitro Diagnostic use. Use the product in compliance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Austria - Occupational Exposure Limits	
Local name	2-Methyl-(2H)-isothiazol-3-on
MAK (mg/m ³)	0.05 mg/m ³ 2-Methyl-(2H)-isothiazol-3-on
Remark (AT)	Sh,H
OEL chemical category (AT)	Skin sensitizer
Regulatory reference	BGBl. II Nr. 186/2015
Germany - Occupational Exposure Limits (TRGS 900)	
Local name	2-Methyl-(2H)-isothiazol-3-on
Occupational exposure limit value (mg/m ³)	0.2 mg/m ³
Switzerland - Occupational Exposure Limits	
Local name	2-méthylisothiazol-3(2H)-one
MAK (mg/m ³)	0.2 mg/m ³ (i) / (e)
KZGW (mg/m ³)	0.4 mg/m ³ (i) / (e)
Critical toxicity	VRS, Skin, Eye / OAW
Notation	S, SS _c / S, SS _c
Regulatory reference	www.suva.ch, 01.07.2019

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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 EN 374. FKM (fluoro rubber). Breakthrough time: < 1 h. Layer thickness: 0.4 mm.

Eye protection:

Chemical goggles or safety glasses. EN 166.

Skin and body protection:

Use chemically protective clothing. Lab coat.

Respiratory protection:

Not required for normal conditions of use.

Personal protective equipment symbol(s):



Environmental exposure controls:

Do not allow into drains or water courses.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid.
Colour	: Not determined.
Odour	: Not determined.
Odour threshold	: Not determined.
pH	: Not determined.
Relative evaporation rate (butylacetate=1)	: Not determined.
Melting point	: Not determined.
Freezing point	: Not determined.
Boiling point	: Not determined.
Flash point	: Not determined.
Auto-ignition temperature	: Not determined.
Decomposition temperature	: Not determined.
Flammability (solid, gas)	: Not determined.
Vapour pressure	: Not determined.
Relative vapour density at 20 °C	: Not determined.
Relative density	: Not determined.
Solubility	: Completely soluble.
Log Pow	: Not determined.
Viscosity, kinematic	: Not determined.
Viscosity, dynamic	: Not determined.
Explosive properties	: Not explosive.
Oxidising properties	: Not oxidising.
Explosive limits	: Not determined.
Particle characteristics	: Not applicable.

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available.

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9.2.2. Other safety characteristics

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. No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

No additional information available.

10.5. Incompatible materials

Strong oxidising agents. Reducing agents. Amines. Mercaptan.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂). Nitrogen oxides. Sulphur oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified.
Acute toxicity (dermal)	: Not classified.
Acute toxicity (inhalation)	: Not classified.
Skin corrosion/irritation	: Not classified.
Serious eye damage/irritation	: Not classified.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified.
Carcinogenicity	: Not classified.
Reproductive toxicity	: Not classified.
STOT-single exposure	: Not classified.
STOT-repeated exposure	: Not classified.
Aspiration hazard	: Not classified.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified.

Hazardous to the aquatic environment, long-term (chronic) : Not classified.

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

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12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

12.7. 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.

Product/Packaging disposal recommendations : Handle uncleaned empty containers as full ones.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

No additional information available.

14.6. Special precautions for user

Overland transport

Not regulated.

Transport by sea

Not regulated.

Air transport

Not regulated.

Inland waterway transport

Not regulated.

Rail transport

Not regulated.

14.7. Maritime transport in bulk according to IMO instruments

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 XIV substances.

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

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15.1.2. National regulations

Germany

Reference to AwSV : Water hazard class (WGK) 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance).

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed.

SZW-lijst van mutagene stoffen : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed.

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product.

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 Rail
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	CAS (Chemical Abstracts Service) number
CSR	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 mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product. This document shall be only used and considered as a guideline requiring appropriate and professional chemical handling of this product with caution or under qualified supervision. This product is not intended for purposes alien to those displayed in section 1, unless being informed adequately by written instructions on handling procedures considering this material. This product shall be used in compliance with the Good Laboratory Practice. All potential dangers involved in the interactions of the described product with additional materials and chemicals are not indicated in this form. The user is the solely responsible agent regarding the product's suitability for the intended use, the product's safe use as well as its safe disposal. No warranty or representation, either explicit or implicit, of merchantability, suitable for a specific purpose or of any other nature is made hereunder with respect to the information set forth or to product which the information refers.

Full text of H- and EUH-statements:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1

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Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Skin Corr. 1B	Skin corrosion/irritation, Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
Skin Sens. 1A	Skin sensitisation, category 1A	
H301	Toxic if swallowed.	
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.	
Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1	H317	Calculation method

SDS EU (REACH Annex II)

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.

MYCOPLASMA PNEUMONIAE VIRCLIA® IgG MONOTEST

VIRCLIA® MYCOPLASMA PNEUMONIAE IgG MONODOSE

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Edition: 4. Date: 09/02/2023



This SDS refers exclusively to: VIRCLIA® MYCOPLASMA PNEUMONIAE IgG MONODOSE.

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

1.1. Product identifier

Product form : Mixture
Product name : **MYCOPLASMA PNEUMONIAE VIRCLIA® IgG MONOTEST**
Trade name : **VIRCLIA® KIT** (VIRCLIA® MYCOPLASMA PNEUMONIAE IgG MONODOSE)
Product code : **VCM062**

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

1.2.1. Relevant identified uses

Industrial/Professional use specifications : For professional use only.
Use of the substance/mixture : *In Vitro* Diagnostic use.

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 +34 958-44 12 64 - F +34 958-51 07 12
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]

Skin sensitisation, category 1 H317

Full text of H statements : see section 16.

Adverse physicochemical, human health and environmental effects

No additional information available.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07: Health hazard/Hazardous to the ozone layer.

Signal word (CLP) :

Warning.

Hazardous ingredients :

2-Methyl-2H-isothiazol-3-one.

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) :

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 - Contaminated work clothing should not be allowed out of the workplace.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 - If on skin: Wash with plenty of water.

P321 - Specific treatment (see supplemental first aid instruction on this label).

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

2.3. Other hazards

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

The mixture does not contain PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	0.01 – 0.05	Acute Tox. 3 (Oral), H301 (ATE= 100 mg/kg bodyweight) Acute Tox. 3 (Dermal), H311 (ATE = 300 mg/kg bodyweight) Acute Tox. 2 (Inhalation), H330 (ATE = 0.05 mg/l/4h) Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1)

Specific concentration limits:

Name	Product identifier	Specific concentration limits
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	(0.0015 =<C < 100) Skin Sens. 1A, H317

Full text of H-statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell. If medical advice is needed, have product container or label at hand.
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 advice.
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/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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	: Water, carbon dioxide (CO ₂), dry chemical powder, foam.
Unsuitable extinguishing media	: No data available.

5.2. Special hazards arising from the substance or mixture

Fire hazard:	: No data available.
Explosion hazard:	: No data available.
Hazardous decomposition products in case of fire:	: No data 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. Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire.

MYCOPLASMA PNEUMONIAE VIRCLIA® IgG MONOTEST

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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. Ensure adequate ventilation, especially in confined areas.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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 (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. See Section 1 for emergency contact information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes. Provide adequate ventilation. Avoid formation of vapours. Do not breathe gas, fumes, vapour or spray.

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.

Storage temperature : 2 - 8 °C.

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

Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

In Vitro Diagnostic use. Use the product in compliance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Austria - Occupational Exposure Limits	
Local name	2-Methyl-(2H)-isothiazol-3-on
MAK (mg/m ³)	0.05 mg/m ³ 2-Methyl-(2H)-isothiazol-3-on
Remark (AT)	Sh,H
OEL chemical category (AT)	Skin sensitizer
Regulatory reference	BGBl. II Nr. 186/2015
Germany - Occupational Exposure Limits (TRGS 900)	
Local name	2-Methyl-(2H)-isothiazol-3-on
Occupational exposure limit value (mg/m ³)	0.2 mg/m ³
Switzerland - Occupational Exposure Limits	
Local name	2-méthylisothiazol-3(2H)-one
MAK (mg/m ³)	0.2 mg/m ³ (i) / (e)
KZGW (mg/m ³)	0.4 mg/m ³ (i) / (e)
Critical toxicity	VRS, Skin, Eye / OAW
Notation	S, SS _c / S, SS _c
Regulatory reference	www.suva.ch, 01.07.2019

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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 EN 374. FKM (fluoro rubber). Breakthrough time: < 1 h. Layer thickness: 0.4 mm.

Eye protection:

Chemical goggles or safety glasses. EN 166.

Skin and body protection:

Use chemically protective clothing. Lab coat.

Respiratory protection:

Not required for normal conditions of use.

Personal protective equipment symbol(s):



Environmental exposure controls:

Do not allow into drains or water courses.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid.
Colour	: Not determined.
Odour	: Not determined.
Odour threshold	: Not determined.
pH	: Not determined.
Relative evaporation rate (butylacetate=1)	: Not determined.
Melting point	: Not determined.
Freezing point	: Not determined.
Boiling point	: Not determined.
Flash point	: Not determined.
Auto-ignition temperature	: Not determined.
Decomposition temperature	: Not determined.
Flammability (solid, gas)	: Not determined.
Vapour pressure	: Not determined.
Relative vapour density at 20 °C	: Not determined.
Relative density	: Not determined.
Solubility	: Completely soluble.
Log Pow	: Not determined.
Viscosity, kinematic	: Not determined.
Viscosity, dynamic	: Not determined.
Explosive properties	: Not explosive.
Oxidising properties	: Not oxidising.
Explosive limits	: Not determined.
Particle characteristics	: Not applicable.

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available.

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9.2.2. Other safety characteristics

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. No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

No additional information available.

10.5. Incompatible materials

Strong oxidising agents. Reducing agents. Amines. Mercaptan.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂). Nitrogen oxides. Sulphur oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified.
Acute toxicity (dermal)	: Not classified.
Acute toxicity (inhalation)	: Not classified.
Skin corrosion/irritation	: Not classified.
Serious eye damage/irritation	: Not classified.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified.
Carcinogenicity	: Not classified.
Reproductive toxicity	: Not classified.
STOT-single exposure	: Not classified.
STOT-repeated exposure	: Not classified.
Aspiration hazard	: Not classified.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified.

Hazardous to the aquatic environment, long-term (chronic) : Not classified.

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

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12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

12.7. 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.

Product/Packaging disposal recommendations : Handle uncleaned empty containers as full ones.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

No additional information available.

14.6. Special precautions for user

Overland transport

Not regulated.

Transport by sea

Not regulated.

Air transport

Not regulated.

Inland waterway transport

Not regulated.

Rail transport

Not regulated.

14.7. Maritime transport in bulk according to IMO instruments

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 XIV substances.

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

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15.1.2. National regulations

Germany

Reference to AwSV : Water hazard class (WGK) 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance).

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed.

SZW-lijst van mutagene stoffen : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed.

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product.

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 Rail
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	CAS (Chemical Abstracts Service) number
CSR	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 mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product. This document shall be only used and considered as a guideline requiring appropriate and professional chemical handling of this product with caution or under qualified supervision. This product is not intended for purposes alien to those displayed in section 1, unless being informed adequately by written instructions on handling procedures considering this material. This product shall be used in compliance with the Good Laboratory Practice. All potential dangers involved in the interactions of the described product with additional materials and chemicals are not indicated in this form. The user is the solely responsible agent regarding the product's suitability for the intended use, the product's safe use as well as its safe disposal. No warranty or representation, either explicit or implicit, of merchantability, suitable for a specific purpose or of any other nature is made hereunder with respect to the information set forth or to product which the information refers.

Full text of H- and EUH-statements:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1

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Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Skin Corr. 1B	Skin corrosion/irritation, Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
Skin Sens. 1A	Skin sensitisation, category 1A	
H301	Toxic if swallowed.	
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.	
Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1	H317	Calculation method

SDS EU (REACH Annex II)

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.

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Edition: 4. Date: 09/02/2023



This SDS refers exclusively to: VIRCLIA® MYCOPLASMA PNEUMONIAE IgM MONODOSE.

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

1.1. Product identifier

Product form	: Mixture
Product name	: MYCOPLASMA PNEUMONIAE VIRCLIA® IgM MONOTEST
Trade name	: VIRCLIA® KIT (VIRCLIA® MYCOPLASMA PNEUMONIAE IgM MONODOSE)
Product code	: VCM064

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

1.2.1. Relevant identified uses

Industrial/Professional use specifications	: For professional use only.
Use of the substance/mixture	: <i>In Vitro</i> Diagnostic use.

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 +34 958-44 12 64 - F +34 958-51 07 12
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]

Skin sensitisation, category 1 H317

Full text of H statements : see section 16.

Adverse physicochemical, human health and environmental effects

No additional information available.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07: Health hazard/Hazardous to the ozone layer.

Signal word (CLP) :

Warning.

Hazardous ingredients :

2-Methyl-2H-isothiazol-3-one.

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) :

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 - If on skin: Wash with plenty of water.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

2.3. Other hazards

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

The mixture does not contain PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	0.01 – 0.05	Acute Tox. 3 (Oral), H301 (ATE= 100 mg/kg bodyweight) Acute Tox. 3 (Dermal), H311 (ATE = 300 mg/kg bodyweight) Acute Tox. 2 (Inhalation), H330 (ATE = 0.05 mg/l/4h) Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1)

Specific concentration limits:

Name	Product identifier	Specific concentration limits
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	(0.0015 =<C < 100) Skin Sens. 1A, H317

Full text of H-statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell. If medical advice is needed, have product container or label at hand.
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 advice.
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/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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	: Water, carbon dioxide (CO ₂), dry chemical powder, foam.
Unsuitable extinguishing media	: No data available.

5.2. Special hazards arising from the substance or mixture

Fire hazard:	: No data available.
Explosion hazard:	: No data available.
Hazardous decomposition products in case of fire:	: No data 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. Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire.

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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. Ensure adequate ventilation, especially in confined areas.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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 (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. See Section 1 for emergency contact information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes. Provide adequate ventilation. Avoid formation of vapours. Do not breathe gas, fumes, vapour or spray.

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.

Storage temperature : 2 - 8 °C.

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

Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

In Vitro Diagnostic use. Use the product in compliance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Austria - Occupational Exposure Limits	
Local name	2-Methyl-(2H)-isothiazol-3-on
MAK (mg/m ³)	0.05 mg/m ³ 2-Methyl-(2H)-isothiazol-3-on
Remark (AT)	Sh,H
OEL chemical category (AT)	Skin sensitizer
Regulatory reference	BGBl. II Nr. 186/2015
Germany - Occupational Exposure Limits (TRGS 900)	
Local name	2-Methyl-(2H)-isothiazol-3-on
Occupational exposure limit value (mg/m ³)	0.2 mg/m ³
Switzerland - Occupational Exposure Limits	
Local name	2-méthylisothiazol-3(2H)-one
MAK (mg/m ³)	0.2 mg/m ³ (i) / (e)
KZGW (mg/m ³)	0.4 mg/m ³ (i) / (e)
Critical toxicity	VRS, Skin, Eye / OAW
Notation	S, SS _c / S, SS _c
Regulatory reference	www.suva.ch, 01.07.2019

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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 EN 374. FKM (fluoro rubber). Breakthrough time: < 1 h. Layer thickness: 0.4 mm.

Eye protection:

Chemical goggles or safety glasses. EN 166.

Skin and body protection:

Use chemically protective clothing. Lab coat.

Respiratory protection:

Not required for normal conditions of use.

Personal protective equipment symbol(s):



Environmental exposure controls:

Do not allow into drains or water courses.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid.
Colour	: Not determined.
Odour	: Not determined.
Odour threshold	: Not determined.
pH	: Not determined.
Relative evaporation rate (butylacetate=1)	: Not determined.
Melting point	: Not determined.
Freezing point	: Not determined.
Boiling point	: Not determined.
Flash point	: Not determined.
Auto-ignition temperature	: Not determined.
Decomposition temperature	: Not determined.
Flammability (solid, gas)	: Not determined.
Vapour pressure	: Not determined.
Relative vapour density at 20 °C	: Not determined.
Relative density	: Not determined.
Solubility	: Completely soluble.
Log Pow	: Not determined.
Viscosity, kinematic	: Not determined.
Viscosity, dynamic	: Not determined.
Explosive properties	: Not explosive.
Oxidising properties	: Not oxidising.
Explosive limits	: Not determined.
Particle characteristics	: Not applicable.

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available.

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9.2.2. Other safety characteristics

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. No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

No additional information available.

10.5. Incompatible materials

Strong oxidising agents. Reducing agents. Amines. Mercaptan.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂). Nitrogen oxides. Sulphur oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified.
Acute toxicity (dermal)	: Not classified.
Acute toxicity (inhalation)	: Not classified.
Skin corrosion/irritation	: Not classified.
Serious eye damage/irritation	: Not classified.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified.
Carcinogenicity	: Not classified.
Reproductive toxicity	: Not classified.
STOT-single exposure	: Not classified.
STOT-repeated exposure	: Not classified.
Aspiration hazard	: Not classified.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified.

Hazardous to the aquatic environment, long-term (chronic) : Not classified.

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

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12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

12.7. 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.

Product/Packaging disposal recommendations : Handle uncleaned empty containers as full ones.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

No additional information available.

14.6. Special precautions for user

Overland transport

Not regulated.

Transport by sea

Not regulated.

Air transport

Not regulated.

Inland waterway transport

Not regulated.

Rail transport

Not regulated.

14.7. Maritime transport in bulk according to IMO instruments

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 XIV substances.

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

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15.1.2. National regulations

Germany

Reference to AwSV : Water hazard class (WGK) 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance).

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed.

SZW-lijst van mutagene stoffen : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed.

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product.

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 Rail
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	CAS (Chemical Abstracts Service) number
CSR	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 mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product. This document shall be only used and considered as a guideline requiring appropriate and professional chemical handling of this product with caution or under qualified supervision. This product is not intended for purposes alien to those displayed in section 1, unless being informed adequately by written instructions on handling procedures considering this material. This product shall be used in compliance with the Good Laboratory Practice. All potential dangers involved in the interactions of the described product with additional materials and chemicals are not indicated in this form. The user is the solely responsible agent regarding the product's suitability for the intended use, the product's safe use as well as its safe disposal. No warranty or representation, either explicit or implicit, of merchantability, suitable for a specific purpose or of any other nature is made hereunder with respect to the information set forth or to product which the information refers.

Full text of H- and EUH-statements:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1

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Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Skin Corr. 1B	Skin corrosion/irritation, Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
Skin Sens. 1A	Skin sensitisation, category 1A	
H301	Toxic if swallowed.	
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.	
Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1	H317	Calculation method

SDS EU (REACH Annex II)

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.

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Edition: 4. Date: 09/02/2023



This SDS refers exclusively to: VIRCLIA® TICK BORNE ENCEPHALITIS IgG MONODOSE.

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

1.1. Product identifier

Product form : Mixture
Product name : **TICK-BORNE ENCEPHALITIS VIRCLIA® IgG MONOTEST**
Trade name : **VIRCLIA® KIT** (VIRCLIA® TICK BORNE ENCEPHALITIS IgG MONODOSE)
Product code : **VCM047**

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

1.2.1. Relevant identified uses

Industrial/Professional use specifications : For professional use only.
Use of the substance/mixture : *In Vitro* Diagnostic use.

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 +34 958-44 12 64 - F +34 958-51 07 12
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]

Skin sensitisation, category 1 H317

Full text of H statements : see section 16.

Adverse physicochemical, human health and environmental effects

No additional information available.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07: Health hazard/Hazardous to the ozone layer.

Signal word (CLP) :

Warning.

Hazardous ingredients :

2-Methyl-2H-isothiazol-3-one.

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) :

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 - If on skin: Wash with plenty of water.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

2.3. Other hazards

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

The mixture does not contain PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	0.01 – 0.05	Acute Tox. 3 (Oral), H301 (ATE= 100 mg/kg bodyweight) Acute Tox. 3 (Dermal), H311 (ATE = 300 mg/kg bodyweight) Acute Tox. 2 (Inhalation), H330 (ATE = 0.05 mg/l/4h) Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1)

Specific concentration limits:

Name	Product identifier	Specific concentration limits
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	(0.0015 =<C < 100) Skin Sens. 1A, H317

Full text of H-statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell. If medical advice is needed, have product container or label at hand.
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 advice.
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/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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	: Water, carbon dioxide (CO ₂), dry chemical powder, foam.
Unsuitable extinguishing media	: No data available.

5.2. Special hazards arising from the substance or mixture

Fire hazard:	: No data available.
Explosion hazard:	: No data available.
Hazardous decomposition products in case of fire:	: No data 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. Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire.

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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. Ensure adequate ventilation, especially in confined areas.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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 (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. See Section 1 for emergency contact information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes. Provide adequate ventilation. Avoid formation of vapours. Do not breathe gas, fumes, vapour or spray.

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.

Storage temperature : 2 - 8 °C.

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

Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

In Vitro Diagnostic use. Use the product in compliance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Austria - Occupational Exposure Limits	
Local name	2-Methyl-(2H)-isothiazol-3-on
MAK (mg/m ³)	0.05 mg/m ³ 2-Methyl-(2H)-isothiazol-3-on
Remark (AT)	Sh,H
OEL chemical category (AT)	Skin sensitizer
Regulatory reference	BGBl. II Nr. 186/2015
Germany - Occupational Exposure Limits (TRGS 900)	
Local name	2-Methyl-(2H)-isothiazol-3-on
Occupational exposure limit value (mg/m ³)	0.2 mg/m ³
Switzerland - Occupational Exposure Limits	
Local name	2-méthylisothiazol-3(2H)-one
MAK (mg/m ³)	0.2 mg/m ³ (i) / (e)
KZGW (mg/m ³)	0.4 mg/m ³ (i) / (e)
Critical toxicity	VRS, Skin, Eye / OAW
Notation	S, SS _c / S, SS _c
Regulatory reference	www.suva.ch, 01.07.2019

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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 EN 374. FKM (fluoro rubber). Breakthrough time: < 1 h. Layer thickness: 0.4 mm.

Eye protection:

Chemical goggles or safety glasses. EN 166.

Skin and body protection:

Use chemically protective clothing. Lab coat.

Respiratory protection:

Not required for normal conditions of use.

Personal protective equipment symbol(s):



Environmental exposure controls:

Do not allow into drains or water courses.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid.
Colour	: Not determined.
Odour	: Not determined.
Odour threshold	: Not determined.
pH	: Not determined.
Relative evaporation rate (butylacetate=1)	: Not determined.
Melting point	: Not determined.
Freezing point	: Not determined.
Boiling point	: Not determined.
Flash point	: Not determined.
Auto-ignition temperature	: Not determined.
Decomposition temperature	: Not determined.
Flammability (solid, gas)	: Not determined.
Vapour pressure	: Not determined.
Relative vapour density at 20 °C	: Not determined.
Relative density	: Not determined.
Solubility	: Completely soluble.
Log Pow	: Not determined.
Viscosity, kinematic	: Not determined.
Viscosity, dynamic	: Not determined.
Explosive properties	: Not explosive.
Oxidising properties	: Not oxidising.
Explosive limits	: Not determined.
Particle characteristics	: Not applicable.

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available.

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9.2.2. Other safety characteristics

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. No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

No additional information available.

10.5. Incompatible materials

Strong oxidising agents. Reducing agents. Amines. Mercaptan.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂). Nitrogen oxides. Sulphur oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified.
Acute toxicity (dermal)	: Not classified.
Acute toxicity (inhalation)	: Not classified.
Skin corrosion/irritation	: Not classified.
Serious eye damage/irritation	: Not classified.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified.
Carcinogenicity	: Not classified.
Reproductive toxicity	: Not classified.
STOT-single exposure	: Not classified.
STOT-repeated exposure	: Not classified.
Aspiration hazard	: Not classified.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified.

Hazardous to the aquatic environment, long-term (chronic) : Not classified.

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

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12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

12.7. 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.

Product/Packaging disposal recommendations : Handle uncleaned empty containers as full ones.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

No additional information available.

14.6. Special precautions for user

Overland transport

Not regulated.

Transport by sea

Not regulated.

Air transport

Not regulated.

Inland waterway transport

Not regulated.

Rail transport

Not regulated.

14.7. Maritime transport in bulk according to IMO instruments

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 XIV substances.

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

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15.1.2. National regulations

Germany

Reference to AwSV : Water hazard class (WGK) 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance).

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed.

SZW-lijst van mutagene stoffen : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed.

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product.

15.2. Chemical safety assessment

No additional information available.

SECTION 16: Other information

Abbreviations and acronyms:

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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	CAS (Chemical Abstracts Service) number
CSR	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 mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product. This document shall be only used and considered as a guideline requiring appropriate and professional chemical handling of this product with caution or under qualified supervision. This product is not intended for purposes alien to those displayed in section 1, unless being informed adequately by written instructions on handling procedures considering this material. This product shall be used in compliance with the Good Laboratory Practice. All potential dangers involved in the interactions of the described product with additional materials and chemicals are not indicated in this form. The user is the solely responsible agent regarding the product's suitability for the intended use, the product's safe use as well as its safe disposal. No warranty or representation, either explicit or implicit, of merchantability, suitable for a specific purpose or of any other nature is made hereunder with respect to the information set forth or to product which the information refers.

Full text of H- and EUH-statements:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1

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Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Skin Corr. 1B	Skin corrosion/irritation, Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
Skin Sens. 1A	Skin sensitisation, category 1A	
H301	Toxic if swallowed.	
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.	
Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1	H317	Calculation method

SDS EU (REACH Annex II)

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.

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
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This SDS refers exclusively to: VIRCLIA® TICK BORNE ENCEPHALITIS IgM MONODOSE.

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

1.1. Product identifier

Product form : Mixture
Product name : **TICK-BORNE ENCEPHALITIS VIRCLIA® IgM MONOTEST**
Trade name : **VIRCLIA® KIT** (VIRCLIA® TICK BORNE ENCEPHALITIS IgM MONODOSE)
Product code : **VCM048**

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

1.2.1. Relevant identified uses

Industrial/Professional use specifications : For professional use only.
Use of the substance/mixture : *In Vitro* Diagnostic use.

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 +34 958-44 12 64 - F +34 958-51 07 12
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]

Skin sensitisation, category 1 H317

Full text of H statements : see section 16.

Adverse physicochemical, human health and environmental effects

No additional information available.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07: Health hazard/Hazardous to the ozone layer.

Signal word (CLP) :

Warning.

Hazardous ingredients :

2-Methyl-2H-isothiazol-3-one.

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) :

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 - If on skin: Wash with plenty of water.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

2.3. Other hazards

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

The mixture does not contain PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	0.01 – 0.05	Acute Tox. 3 (Oral), H301 (ATE= 100 mg/kg bodyweight) Acute Tox. 3 (Dermal), H311 (ATE = 300 mg/kg bodyweight) Acute Tox. 2 (Inhalation), H330 (ATE = 0.05 mg/l/4h) Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1)

Specific concentration limits:

Name	Product identifier	Specific concentration limits
2-Methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9 REACH-No.: Not available	(0.0015 =<C < 100) Skin Sens. 1A, H317

Full text of H-statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell. If medical advice is needed, have product container or label at hand.
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 advice.
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/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

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	: Water, carbon dioxide (CO ₂), dry chemical powder, foam.
Unsuitable extinguishing media	: No data available.

5.2. Special hazards arising from the substance or mixture

Fire hazard:	: No data available.
Explosion hazard:	: No data available.
Hazardous decomposition products in case of fire:	: No data 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. Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire.

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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. Ensure adequate ventilation, especially in confined areas.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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 (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. See Section 1 for emergency contact information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes. Provide adequate ventilation. Avoid formation of vapours. Do not breathe gas, fumes, vapour or spray.

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.

Storage temperature : 2 - 8 °C.

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

Special rules on packaging : Keep only in original container.

7.3. Specific end use(s)

In Vitro Diagnostic use. Use the product in compliance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Austria - Occupational Exposure Limits	
Local name	2-Methyl-(2H)-isothiazol-3-on
MAK (mg/m ³)	0.05 mg/m ³ 2-Methyl-(2H)-isothiazol-3-on
Remark (AT)	Sh,H
OEL chemical category (AT)	Skin sensitizer
Regulatory reference	BGBl. II Nr. 186/2015
Germany - Occupational Exposure Limits (TRGS 900)	
Local name	2-Methyl-(2H)-isothiazol-3-on
Occupational exposure limit value (mg/m ³)	0.2 mg/m ³
Switzerland - Occupational Exposure Limits	
Local name	2-méthylisothiazol-3(2H)-one
MAK (mg/m ³)	0.2 mg/m ³ (i) / (e)
KZGW (mg/m ³)	0.4 mg/m ³ (i) / (e)
Critical toxicity	VRS, Skin, Eye / OAW
Notation	S, SS _c / S, SS _c
Regulatory reference	www.suva.ch, 01.07.2019

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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 EN 374. FKM (fluoro rubber). Breakthrough time: < 1 h. Layer thickness: 0.4 mm.

Eye protection:

Chemical goggles or safety glasses. EN 166.

Skin and body protection:

Use chemically protective clothing. Lab coat.

Respiratory protection:

Not required for normal conditions of use.

Personal protective equipment symbol(s):



Environmental exposure controls:

Do not allow into drains or water courses.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid.
Colour	: Not determined.
Odour	: Not determined.
Odour threshold	: Not determined.
pH	: Not determined.
Relative evaporation rate (butylacetate=1)	: Not determined.
Melting point	: Not determined.
Freezing point	: Not determined.
Boiling point	: Not determined.
Flash point	: Not determined.
Auto-ignition temperature	: Not determined.
Decomposition temperature	: Not determined.
Flammability (solid, gas)	: Not determined.
Vapour pressure	: Not determined.
Relative vapour density at 20 °C	: Not determined.
Relative density	: Not determined.
Solubility	: Completely soluble.
Log Pow	: Not determined.
Viscosity, kinematic	: Not determined.
Viscosity, dynamic	: Not determined.
Explosive properties	: Not explosive.
Oxidising properties	: Not oxidising.
Explosive limits	: Not determined.
Particle characteristics	: Not applicable.

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available.

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9.2.2. Other safety characteristics

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. No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

No additional information available.

10.5. Incompatible materials

Strong oxidising agents. Reducing agents. Amines. Mercaptan.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂). Nitrogen oxides. Sulphur oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified.
Acute toxicity (dermal)	: Not classified.
Acute toxicity (inhalation)	: Not classified.
Skin corrosion/irritation	: Not classified.
Serious eye damage/irritation	: Not classified.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified.
Carcinogenicity	: Not classified.
Reproductive toxicity	: Not classified.
STOT-single exposure	: Not classified.
STOT-repeated exposure	: Not classified.
Aspiration hazard	: Not classified.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified.

Hazardous to the aquatic environment, long-term (chronic) : Not classified.

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

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12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

12.7. 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.

Product/Packaging disposal recommendations : Handle uncleaned empty containers as full ones.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

No additional information available.

14.6. Special precautions for user

Overland transport

Not regulated.

Transport by sea

Not regulated.

Air transport

Not regulated.

Inland waterway transport

Not regulated.

Rail transport

Not regulated.

14.7. Maritime transport in bulk according to IMO instruments

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 XIV substances.

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

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15.1.2. National regulations

Germany

Reference to AwSV : Water hazard class (WGK) 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance).

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed.

SZW-lijst van mutagene stoffen : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed.

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed.

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product.

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 Rail
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	CAS (Chemical Abstracts Service) number
CSR	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 mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product. This document shall be only used and considered as a guideline requiring appropriate and professional chemical handling of this product with caution or under qualified supervision. This product is not intended for purposes alien to those displayed in section 1, unless being informed adequately by written instructions on handling procedures considering this material. This product shall be used in compliance with the Good Laboratory Practice. All potential dangers involved in the interactions of the described product with additional materials and chemicals are not indicated in this form. The user is the solely responsible agent regarding the product's suitability for the intended use, the product's safe use as well as its safe disposal. No warranty or representation, either explicit or implicit, of merchantability, suitable for a specific purpose or of any other nature is made hereunder with respect to the information set forth or to product which the information refers.

Full text of H- and EUH-statements:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1

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Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
Skin Corr. 1B	Skin corrosion/irritation, Category 1B	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
Skin Sens. 1A	Skin sensitisation, category 1A	
H301	Toxic if swallowed.	
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.	
Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1	H317	Calculation method

SDS EU (REACH Annex II)

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