CHLAMYDOPHILA PNEUMONIAE ELISA IgG

Safety Data Sheet

According to Regulation (EU) 2015/830

Revision date: 01/06/2018

ELISA kit includes several mixtures, which have all been evaluated for classification. This SDS refers exclusively to: **Vircell Stop Reagent** and **Vircell Wash Buffer** since they are the only hazardous mixtures within the kit, According to Regulation (EC) No. 1272/2008 [CLP]

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

1.1. Product identifier

Product name: CHLAMYDOPHILA PNEUMONIAE ELISA IgG

Product code: G1007

Product form: Mixture

Trade name: ELISA Kit.

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

1.2.1. Relevant identified uses

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 441264 - F +34 958510712
customerservice@vircell.com

1.4. Emergency telephone number

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

SECTION 2: Composition/information on components

Component name	Component classification According to regulations (EC) no. 1272/2008 [CLP]	Kit Configuration
Vircell Stop Reagent	H314	1 x 15 mL
Vircell Wash Buffer	H317	1 x 50 mL (20x)

SECTION 3: Disclaimer

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. The displayed information of this SDS comply with Annex II of the COMMISSION REGULATION (EU) No 2015/830 of 01 June 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, authorization and Restriction of Chemicals (REACH), and in accordance with ANSI “Standard for Hazardous Industrial Chemicals - Safety Data Sheets – Preparation” (ANSI Z400.1-2004) as recommended by US OSHA

This SDS section refers exclusively to: Vircell Stop Reagent

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

1.1. Product identifier

Product name: CHLAMYDOPHILA PNEUMONIAE ELISA IgG

Product code: G1007

Product form: Mixture

Trade name: ELISA Kit (Vircell Stop Reagent)

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

1.2.1. Relevant identified uses

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
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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 corrosion/irritation Category 1A	H314

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):	 GHS05
Signal word (CLP):	Danger
Hazard statements (CLP):	H314 - Causes severe skin burns and eye damage
Precautionary statements (CLP):	P280 - Wear eye protection, face protection, protective clothing, protective gloves P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310 - Immediately call a doctor, a POISON CENTER P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower P363 - Wash contaminated clothing before reuse

2.3. Other hazards not contributing to the classification

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

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification According to Regulation (EC) No. 1272/2008 [CLP]
Sulfuric acid	(CAS No) 7664-93-9 (EC No) 231-639-5 (EC index No) 016-020-00-8 (REACH- No) not available	<3	Skin Corr. 1A, H314

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Sulfuric acid	(CAS No) 7664-93-9 (EC No) 231-639-5 (EC index No) 016-020-00-8 (REACH- No) not available	(5 =< C < 15) Eye Irrit. 2, H319 (5 =< C < 15) Skin Irrit. 2, H315 (C >= 15) Skin Corr. 1A, H314

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 orally 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 attention

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

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

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

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

Symptoms/injuries after skin contact: Causes severe skin burns and eye damage

Symptoms/injuries after eye contact: Risk of damage to eyes

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: Not flammable

Explosion hazard: Product is not explosive

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

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

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 inert material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Wash with plenty of soap and water. Consult the appropriate authorities about waste disposal

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

6.4. Reference to other sections

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

Section 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 good ventilation in proper area in order to avoid vapour formation. Do not breath fume/gas/vapours/dust/mist/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

Technical measure: Comply with applicable regulations

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

Storage temperature: 2 – 30°C

Special rules on packaging Keep only in original container

7.3. Specific end use(s)

This reagent is intended for In Vitro Diagnostic use. Use the product in compliance with the Good Laboratory Practice

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sulfuric acid (7664-93-9)		
EU	IOELV TWA (mg/m³)	0,05 mg/m³ (taking into account potential limitations and interferences which take place in the presence of other Sulphur compounds-mist)
Austria	MAK (mg/m³)	0,1 mg/m³ (corresponds to 0.05 mg/m³ Thoracic-inhalable fraction)
Austria	MAK Short time value (mg/m³)	0,2 mg/m³ (inhalable fraction)
Belgium	Limit value (mg/m³)	0,2 mg/m³
Bulgaria	OEL TWA (mg/m³)	0,05 mg/m³ (When choosing a suitable method for monitoring exposure should take into account potential constraints and interactions that may occur in the presence of other sulfur compounds-respirable aerosol)
Croatia	GVI (granična vrijednost izloženosti) (mg/m³)	0,05 mg/m³
Cyprus	OEL TWA (mg/m³)	0,05 mg/m³ (vapor)
Czech Republic	Expoziční limity (PEL) (mg/m³)	1 mg/m³ 0,05 mg/m³ (concentrated-mist)
Denmark	Grænseværdie (langvarig) (mg/m³)	0,05 mg/m³ (thoracic fraction-mist)
Estonia	OEL TWA (mg/m³)	1 mg/m³ (fume)
Finland	HTP-arvo (8h) (mg/m³)	0,05 mg/m³
Finland	HTP-arvo (15 min)	0,1 mg/m³
France	VME (mg/m³)	0,05 mg/m³ (thoracic fraction)
France	VLE (mg/m³)	3 mg/m³
Germany	TRGS 900 Occupational exposure limit value (mg/m³)	0,1 mg/m³ (The risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed-inhalable fraction)
Gibraltar	OEL TWA (mg/m³)	0,05 mg/m³ (when selecting an appropriate exposure monitoring method, account should be taken of potential limitations and interferences that may arise in the presence of other sulphur compounds-thoracic fraction)
Greece	OEL TWA (mg/m³)	0,05 mg/m³ (mist)
Hungary	AK-érték	0,05 mg/m³
Ireland	OEL (8 hours ref) (ppm)	0,05 ppm

Sulfuric acid (7664-93-9)		
Ireland	OEL (15 min ref) (ppm)	0,15 ppm (calculated)
Italy	OEL TWA (mg/m³)	0,05 mg/m³ (When choosing a suitable method for monitoring exposure should take into account potential constraints and interactions that may occur in the presence of other sulfur compounds, respirable fraction-thoracic fraction, mist)
Latvia	OEL TWA (mg/m³)	0,05 mg/m³ (possible limitations and the impact that may result from the presence of other Sulfur components should be taken into account when choosing an appropriate exposure monitoring method-fog, which is defined as the thoracic fraction)
Lithuania	IPRV (mg/m³)	0,05 mg/m³ (vapor)
Lithuania	TPRV (mg/m³)	3 mg/m³ (fog-vapor)
Luxembourg	OEL TWA (mg/m³)	0,05 mg/m³
Malta	OEL TWA (mg/m³)	0,05 mg/m³ (mist)
Netherlands	Grenswaarde TGG 8H (mg/m³)	0,05 mg/m³ (defined as thoracic fraction-mist)
Poland	NDS (mg/m³)	0,05 mg/m³ (thoracic fraction)
Portugal	OEL TWA (mg/m³)	0,05 mg/m³ (thoracic fraction-mist)
Romania	OEL TWA (mg/m³)	0,05 mg/m³
Slovakia	NPHV (priemerná) (mg/m³)	0,1 mg/m³
Slovenia	OEL TWA (mg/m³)	0,05 mg/m³ (inhalable fraction, fog)
Spain	VLA-ED (mg/m³)	0,05 mg/m³ (indicative limit value-mist)
Sweden	nivågränsvärde (NVG) (mg/m³)	0,1 mg/m³
Sweden	kortidsvärde (KTV) (mg/m³)	0,2 mg/m³
United Kingdom	WEL TWA (mg/m³)	0,05 mg/m³ (mist)
Norway	Grenseverdier (AN) (mg/m³)	0,1 mg/m³ (inhalable fraction)
Norway	Grenseverdier (Korttidsverdi) (mg/m3)	0,1 mg/m³ (inhalable fraction)
Switzerland	VME (mg/m³)	0,1 mg/m³ (inhalable dust)
Switzerland	VLE (mg/m³)	0,1 mg/m³ (inhalable dust)
Australia	TWA (mg/m³)	1 mg/m³
Australia	STEL (mg/m³)	3 mg/m³
Canada (Quebec)	VECD (mg/m³)	3 mg/m³
Canada (Quebec)	VEMP (mg/m³)	1 mg/m³
USA - ACGIH	ACGIH TWA (mg/m³)	0,2 mg/m³ (thoracic fraction)
USA - IDLH	US IDLH (mg/m³)	15 mg/m³
USA - NIOSH	NIOSH REL (TWA) (mg/m³)	1 mg/m³
USA - OSHA	OSHA PEL (TWA) (mg/m³)	1 mg/m³

8.2. Exposure controls

Appropriate engineering controls: Provide adequate ventilation

Personal protective equipment: Gloves. Protective goggles. Protective clothing

Hand protection:	Wear suitable gloves tested to EN374
Eye protection:	Chemical goggles or safety glasses
Skin and body protection:	Use chemically protective clothing. Lab coat
Respiratory protection:	Respiratory protection equipment not absolutely necessary
Environmental exposure controls:	Do not let product enter drains
Other information:	Do not drink or smoke while using it

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

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

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No data avaliable

10.2. Chemical stability

Stable under normal conditions until the expiration date displayed on the box and on the labels when product stored at 2 – 30^{o}C

10.3. Possibility of hazardous reactions

No polymerization. No dangerous reactions reported under normal conditions of use

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong oxidizing agents

10.6. Hazardous decomposition products

Hazardous decomposition products under fire conditions: Sulphur oxides

Other decomposition products: No data available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity:	Not classified
Skin corrosion/irritation:	Causes severe skin burns and eye damage
Serious eye damage/irritation:	Serious eye damage, category 1, implicit
Respiratory or skin sensitisation:	Not classified
Germ cell mutagenicity:	Not classified
Carcinogenicity:	Not classified
Reproductive toxicity:	Not classified
Specific target organ toxicity (single exposure):	Not classified
Specific target organ toxicity (repeated exposure):	Not classified
Aspiration hazard:	Not classified

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

The substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
The substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods:	Consult the appropriate local waste disposal expert about waste disposal
Product/Packaging disposal recommendations:	Handle uncleaned empty containers as full ones

SECTION 14: Transport information

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

14.1. UN number

UN-No. (ADR):	2796
UN-No. (IMDG):	2796
UN-No. (IATA):	2796
UN-No. (ADN):	2796
UN-No. (RID):	2796

14.2. UN proper shipping name

Proper Shipping Name (ADR):	SULPHURIC ACID
Proper Shipping Name (IMDG):	SULPHURIC ACID
Proper Shipping Name (IATA):	SULPHURIC ACID
Proper Shipping Name (ADN):	SULPHURIC ACID
Proper Shipping Name (RID):	SULPHURIC ACID
Transport document description:	UN 2796 SULPHURIC ACID, 8, II, (E)
Transport document description (IMDG):	UN 2796 SULPHURIC ACID, 8, II

Transport document description (IATA):	UN 2796 Sulphuric acid, 8, II
Transport document description (ADN):	UN 2796 SULPHURIC ACID, 8, II
Transport document description (RID):	UN 2796 SULPHURIC ACID, 8, II

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR):	8
Danger labels (ADR):	8

IMDG

Transport hazard class(es) (IMDG):	8
Danger labels (IMDG):	8

IATA

Transport hazard class(es) (IATA):	8
Hazard labels (IATA):	8

ADN

Transport hazard class(es) (ADN):	8
Danger labels (ADN):	8

RID

Transport hazard class(es) (RID):	8
Danger labels (RID):	8

14.4. Packing group

Packing group (ADR):	II
Packing group (IMDG):	II
Packing group (IATA):	II
Packing group (ADN):	II
Packing group (RID):	II

14.5. Environmental hazards

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

14.6. Special precautions for user

- Overland transport

Classification code (ADR) :	C1
Limited quantities (ADR):	1l
Excepted quantities (ADR):	E2
Packing instructions (ADR):	P001, IBC02
Mixed packing provisions (ADR):	MP15
Portable tank and bulk container instructions (ADR):	T8
Portable tank and bulk container special provisions (ADR):	TP2
Tank code (ADR):	L4BN
Vehicle for tank carriage:	AT
Transport category (ADR):	2
Hazard identification number (Kemler No.):	80
Orange plates:	
Tunnel restriction code (ADR):	E
EAC code:	2R

- Transport by sea

Limited quantities (IMDG):	1 L
Excepted quantities (IMDG):	E2
Packing instructions (IMDG):	P001
IBC packing instructions (IMDG):	IBC02
IBC special provisions (IMDG):	B20
Tank instructions (IMDG):	T8
Tank special provisions (IMDG):	TP2
EmS-No. (Fire):	F-A
EmS-No. (Spillage):	S-B
Stowage category (IMDG):	B
Properties and observations (IMDG):	Colourless liquid, mixture not exceeding 1.405 relative density. Highly corrosive to most metals. Causes burns to skin, eyes and mucous membranes

- Air transport

PCA Excepted quantities (IATA):	E2
PCA Limited quantities (IATA):	Y840
PCA limited quantity max net quantity (IATA) :	0.5L
PCA packing instructions (IATA):	851
PCA max net quantity (IATA):	1L
CAO packing instructions (IATA):	855

CAO max net quantity (IATA):	30L
ERG code (IATA):	8L

- Inland waterway transport

Classification code (ADN) :	C1
Limited quantities (ADN):	1 L
Excepted quantities (ADN):	E2
Carriage permitted (ADN):	T
Equipment required (ADN):	PP, EP
Number of blue cones/lights (ADN):	0

- Rail transport

Classification code (RID):	C1
Limited quantities (RID):	1L
Excepted quantities (RID):	E2
Packing instructions (RID):	P001, IBC02
Mixed packing provisions (RID):	MP15
Portable tank and bulk container instructions (RID):	T8
Portable tank and bulk container special provisions (RID):	TP2
Tank codes for RID tanks (RID):	L4BN
Transport category (RID):	2
Colis express (express parcels) (RID):	CE6
Hazard identification number (RID):	80

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XVI substances

15.1.2. National regulations

Germany

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

Netherlands

SZW-lijst van kankerverwekkende stoffen:	Sulfuric acid is 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

Recommendations Danish Regulation:	Young people below the age of 18 years are not allowed to use 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	Chemical Abstracts Service
CSR	Chemical Safety Report

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

Full text of H- and EUH-statements:

Skin Corr. 1A	Skin corrosion/irritation Category 1A
H314	Causes severe skin burns and eye damage

Classification According to Regulation (EC) Nr. 1272/2008	**Classification procedure**
Skin corrosion/irritation, Category 1A H314	Expert judgement

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 ELISA IgG
Vircell Wash buffer

Safety Data Sheet

According to Regulation (EU) 2015/830

This SDS section refers exclusively to: Vircell Wash Buffer

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

1.1. Product identifier

Product name:	CHLAMYDOPHILA PNEUMONIAE ELISA IgG
Product code:	G1007
Product form:	Mixture
Trade name:	ELISA Kit (Vircell Wash Buffer)

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

1.2.1. Relevant identified uses

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
Signal word (CLP):	Warning
Hazardous ingredients:	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H - isothiazol-3-one [EC no. 220-239-6] (3:1),
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 eye protection, face protection, protective clothing, protective gloves 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 not contributing to the classification

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

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification According to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1),	(CAS-No.) 55965-84-9 (EC Index-No.) 613-167-00-5	0.003	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Inhalation:dust,mist), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1),	(CAS-No.) 55965-84-9 (EC Index-No.) 613-167-00-5	(C >= 0.0015) Skin Sens. 1, H317 (0.06 =<C < 0.6) Eye Irrit. 2, H319 (0.06 =<C < 0.6) Skin Irrit. 2, H315 (C >= 0.6) Skin Corr. 1B, H314

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 orally 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 attention

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

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

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

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

Symptoms/injuries: 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. Avoid fire-fighting water from entering environment

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

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 or inert material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Wash with plenty of soap and water. Consult the appropriate authorities about waste disposal
Other information:	Do not allow uncontrolled discharge of product into the environment

6.4. Reference to other sections

For disposal of residues refer to section 13 : Disposal considerations. For further information refer to section 8: "Exposure controls/personal protection". 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 good ventilationin proper area in order to avoid vapour formation. Do not breath fume/gas/vapours/dust/mist/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. Store in a well-ventilated place. Keep cool
Heat and ignition sources:	Keep away from open flames, hot surfaces and sources of ignition
Storage temperature:	2 – 8°C
Special rules on packaging:	Keep only in original container

7.3. Specific end use(s)

This reagent is intended for In Vitro Diagnostic use. Use this product in agreement with the Good Laboratory Practice

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:	Provide adequate ventilation
Personal protective equipment:	Gloves. Protective goggles. Protective clothing
Hand protection:	Wear suitable gloves tested to EN374
Eye protection:	Chemical goggles or safety glasses
Skin and body protection:	Use chemically protective clothing. Lab coat
Respiratory protection:	Respiratory protection equipment not absolutely necessary
Environmental exposure controls:	Avoid release to the environment
Other information:	Do not drink or smoke while using it

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Colourless
Odour:	No data available
Odour threshold:	No data available
pH:	No data available
Relative evaporation rate (butylacetate=1):	No data available
Melting point:	No data available
Freezing point:	No data available
Boiling point:	No data available
Flash point:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Flammability (solid, gas):	No data available
Vapour pressure:	No data available
Relative vapour density at 20 °C:	No data available
Relative density:	No data available
Solubility:	Completely soluble
Log Pow:	No data available
Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
Explosive properties:	Not explosive
Oxidising properties:	Not oxidising
Explosive limits:	No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available

10.2. Chemical stability

Stable under normal conditions until the expiration date displayed on the box and on the labels when product stored at 2–8°C

10.3. Possibility of hazardous reactions

No polymerization. No dangerous reactions reported under normal conditions of use

10.4. Conditions to avoid

No data available

10.5. Incompatible materials

Strong oxidizing agents. Reducing agents, Amines, Mercaptans

10.6. Hazardous decomposition products

Hazardous decomposition products under fire conditions: Carbon oxydes (CO, CO2). Nitrogen oxides (NOx) and sulfur oxides

Other decomposition products: Data no available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

SECTION 12: Ecological information

12.1. Toxicity

Acute aquatic toxicity:	No data available
Chronic aquatic toxicity:	No data available

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

The substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
The substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods:	Consult the appropriate local waste disposal expert about waste disposal
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				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable.	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

- Overland transport

Not applicable

- Transport by sea

Not applicable

- Air transport

Not applicable

- Inland waterway transport

Not applicable

- Rail transport

Not applicable

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

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

Netherlands

SZW-lijst van kankerverwekkende stoffen:	Sulfuric acid is 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

Recommendations Danish Regulation:	Young people below the age of 18 years are not allowed to use 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	Chemical Abstracts Service number
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

Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Sens. 1	Skin sensitisation, Category 1
H301	Toxic if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H331	Toxic 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