COVID-19 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:
 COVID-19 ELISA IgG

 Product code:
 G1032

 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

S	SECTION 2: Composition/information on components		
	Component name	Component classification	Kit Configuration
		According to regulations (EC) no. 1272/2008 [CLP]	
ĺ	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

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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: COVID-19 ELISA IgG Product code: G1032 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 18016 Granada - Spain T +34 958 441264 - F +34 958510712 customerservice@vircell.com

1.4. Emergency telephone number

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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

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

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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	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 (CO2), dry chemical powder, foam		
Unsuitable extinguishing media	No data available		
5.2. Special hazards arising from the s	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

6.2. Environmental precautions

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

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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:	e 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:	ge 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	4-93-9)	
EU	IOELV TWA (mg/m³)	0,05 mg/m ³ (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/m ³ (corresponds to 0.05 mg/m ³ Thoracic-inhalable fraction)
Austria	MAK Short time value (mg/m ³)	0,2 mg/m ³ (inhalable fraction)
Belgium	Limit value (mg/m ³)	0,2 mg/m ³
Bulgaria	OEL TWA (mg/m³)	0,05 mg/m ³ (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/m ³)	0,05 mg/m ³
Cyprus	OEL TWA (mg/m³)	0,05 mg/m ³ (vapor)
Czech Republic	Expoziční limity (PEL) (mg/m ³)	1 mg/m ³ 0,05 mg/m ³ (concentrated-mist)
Denmark	Grænseværdie (langvarig) (mg/m ³)	0,05 mg/m ³ (thoracic fraction-mist)
Estonia	OEL TWA (mg/m³)	1 mg/m³ (fume)
Finland	HTP-arvo (8h) (mg/m ³)	0,05 mg/m ³
Finland	HTP-arvo (15 min)	0,1 mg/m ³
France	VME (mg/m ³)	0,05 mg/m ³ (thoracic fraction)
France	VLE (mg/m ³)	3 mg/m ³
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	0,1 mg/m ³ (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/m ³ (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/m ³ (mist)
Hungary	AK-érték	0,05 mg/m ³
Ireland	OEL (8 hours ref) (ppm)	0,05 ppm
Ireland	OEL (15 min ref) (ppm)	0,15 ppm (calculated)

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Sulfuric acid (7664-	93-9)	
Italy	OEL TWA (mg/m³)	0,05 mg/m ³ (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/m ³ (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/m ³)	3 mg/m ³ (fog-vapor)
Luxembourg	OEL TWA (mg/m³)	0,05 mg/m ³
Malta	OEL TWA (mg/m ³)	0,05 mg/m³ (mist)
Netherlands	Grenswaarde TGG 8H (mg/m ³)	0,05 mg/m ³ (defined as thoracic fraction-mist)
Poland	NDS (mg/m ³)	0,05 mg/m ³ (thoracic fraction)
Portugal	OEL TWA (mg/m³)	0,05 mg/m ³ (thoracic fraction-mist)
Romania	OEL TWA (mg/m ³)	0,05 mg/m ³
Slovakia	NPHV (priemerná) (mg/m³)	0,1 mg/m ³
Slovenia	OEL TWA (mg/m³)	0,05 mg/m ³ (inhalable fraction, fog)
Spain	VLA-ED (mg/m ³)	0,05 mg/m ³ (indicative limit value-mist)
Sweden	nivågränsvärde (NVG) (mg/m³)	0,1 mg/m ³
Sweden	kortidsvärde (KTV) (mg/m³)	0,2 mg/m ³
United Kingdom	WEL TWA (mg/m³)	0,05 mg/m³ (mist)
Norway	Grenseverdier (AN) (mg/m ³)	0,1 mg/m ³ (inhalable fraction)
Norway	Grenseverdier (Korttidsverdi) (mg/m3)	0,1 mg/m ³ (inhalable fraction)
Switzerland	VME (mg/m ³)	0,1 mg/m³ (inhalable dust)
Switzerland	VLE (mg/m ³)	0,1 mg/m ³ (inhalable dust)
Australia	TWA (mg/m³)	1 mg/m ³
Australia	STEL (mg/m³)	3 mg/m ³
Canada (Quebec)	VECD (mg/m ³)	3 mg/m ³
Canada (Quebec)	VEMP (mg/m ³)	1 mg/m ³
USA - ACGIH	ACGIH TWA (mg/m³)	0,2 mg/m ³ (thoracic fraction)
USA - IDLH	US IDLH (mg/m³)	15 mg/m ³
USA - NIOSH	NIOSH REL (TWA) (mg/m³)	1 mg/m ³
USA - OSHA	OSHA PEL (TWA) (mg/m³)	1 mg/m ³

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	

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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	No data avaliable		
10.2. Chemical stability	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°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		

Serious eye damage/irritation:	Serious eye damage, category 1, impli
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	

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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): Danger labels (ADR):



8 8



IMDG

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

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ΙΑΤΑ	
IATA Transport hazard class(es) (IATA):	8
Hazard labels (IATA):	8
	0
	8
ADN	
Transport hazard class(es) (ADN):	8
Danger labels (ADN):	8
	8
RID	
Transport hazard class(es) (RID):	8
Danger labels (RID):	8
14.4. Packing group	8
14.4. Packing group Packing group (ADR): Packing group	II .
Packing group (ADK). Packing group (IMDG):	
Packing group (IATA):	
Packing group (ADN):	II
Packing group (RID):	"
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	<u>64</u>
Classification code (ADR) :	C1
Limited quantities (ADR):	11
Excepted quantities (ADR):	E2
Packing instructions (ADR):	P001, IBC02
Mixed packing provisions (ADR):	MP15
Portable tank and bulk container instructions (ADR):	Т8

(ADR):

Portable tank and bulk container special provisions

TP2

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According to Regulation (EU) 2015/830	
Tank code (ADR):	L4BN
Vehicle for tank carriage:	AT
Transport category (ADR):	2
Hazard identification number (Kemler No.):	80
Orange plates:	80 2796
Tunnel restriction code (ADR):	E
EAC code:	2R
- Transport by sea	
Limited quantities (IMDG):	1L
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):	В
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):	1L
Excepted quantities (ADN):	E2
Carriage permitted (ADN):	Т
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):	Τ8
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

According to Regulation (EU) 2015/830

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XVI substances

15.1.2. National regulations

Germany

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

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

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	

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		

According to Regulation (EU) 2015/830

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

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SECTION 1: Identification of the substance/mixture and of the company/undertaking		
1.	Product identifier	
	ct name:	COVID-19 ELISA IgG
	ct code:	G1032
	ct form:	Mixture
	name:	ELISA Kit (Vircell Wash Buffer)
.2.	Relevant identified uses of the substance	
L.2.1.	Relevant identified uses	
	ssional use specifications:	For professional use only
Use of	f the substance/mixture:	In Vitro Diagnostic use
.2.2.	Uses advised against	
lo addi	tional information available	
.3.	Details of the supplier of the safety data	sheet
	LL, S.L.	
-	e Tecnológico de la Salud, Avicena 8	
	i Granada - Spain 958-44 12 64 - F +34 958-51 07 12	
	merservice@vircell.com	
.4.	Emergency telephone number	
	gency number:	112 (24 hour service) – applicable to EU countries only
.1. Classific	Classification of the substance or mixture cation According to Regulation (EC) No. 1272	-
	ensitisation, Category 1 t of H statements: see section 16	H317
Adverse	e physicochemical, human health and enviro	nmental effects:
No addi	tional information available	
2.2.	Label elements	
ahallin	g According to Regulation (EC) No. 1272/200	
	d pictograms (CLP):	GH507
	word (CLP):	Warning
Signal	dous 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),
		H317 - May cause an allergic skin reaction
Hazar	d statements (CLP):	nsi/ - May cause an anergic skin reaction

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

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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]
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

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)="" 2,="" <="" eye="" h319<br="" irrit.="">(0.06 =<c 0.6)="" 2,="" <="" h315<br="" irrit.="" skin="">(C >= 0.6) Skin Corr. 1B, H314</c></c>

Full text of H-statements: see section 16

SECTION 4: First aid measures			
4.1. Description of first aid meas	ures		
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 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 (CO2), dry chemical powder, foam	
Unsuitable extinguishing media:		No data available	
5.2.	5.2. Special hazards arising from the substance or mixture		
Fire h	azard:	No data available	
Explos	sion hazard:	No data available	
Hazardous decomposition products in case of fire:		No data available	
5.3.	Advice for firefighters		
Preca	utionary measures fire:	Evacuate the personnel away from the fumes	
Prote	ctive 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	

According to Regulation (EU) 2015/830



SECTION 6: Accidental release measures			
6.1.	Personal precautions, protective equipment and emergency procedures		
6.1.1.	For non-emergency personnel		
Emerg	ency 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 re	lease to the environment. Prevent entry to	sewers and public waters	
6.3.	Methods and material for containment a	and cleaning up	
For co	ntainment :	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 vapou 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, inclue	ding 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)	

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



Safety Data Sheet

According to Regulation (EU) 2015/830



SECTION 9: Physical and chemical propert	ies
9.1. Information on basic physical and chemic	al 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
lammability (solid, gas):	No data available
/apour 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: St	ability and	d reactivity
SECTION 10. 30	ubility all	

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

ECTION 11: Toxicological information			
1.1. 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		

According to Regulation (EU) 2015/830



Respir	atory or skin sensitisation :	May cause an allergic skin reaction	
Germ	cell mutagenicity:	Not classified	
Carcin	ogenicity:	Not classified	
Repro	ductive toxicity:	Not classified	
STOT-	single exposure:	Not classified	
STOT-	repeated exposure:	Not classified	
Aspira	tion hazard:	Not classified	
SECTIO	ON 12: Ecological information		
12.1.	Toxicity		
Acute	aquatic toxicity:	No data available	
Chron	ic 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 addi	tional information available		
12.5.	Results of PBT and vPvB assessment		
The sub	stance/mixture does not meet the PBT criteria o	f REACH regulation, annex XIII	
The sub	The substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII		
12.6.	Other adverse effects		
No addi	tional information available		
SECTIO	ON 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:

Consult the appropriate local waste disposal expert about waste disposal Handle uncleaned empty containers as full ones

SECTION 14: Transport information

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

ADR	IMDG	ΙΑΤΑ	ADN	RID	
14.1. UN numbe	er	· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·		
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	14.3. Transport hazard class(es)				
Not applicable Not applicable Not applicable Not applicable Not applicable		Not applicable			
14.4. Packing gr	14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	
14.5. Environme	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

Safety Data Sheet

According to Regulation (EU) 2015/830



- 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	Is not subject of the 12. BlmSchV (Hazardous Incident Ordinance)
Immission Control Act - 12.BImSchV	

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

Safety Data Sheet

According to Regulation (EU) 2015/830



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 de	erive the classification	n for mixtures According to Regulation (EC) 1272/2008 [CLP]:
Skin Sens. 1	H317	Calculation method

SDS EU (REACH Annex II)

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