# CYTOMEGALOVIRUS ELISA IgG

# Safety Data Sheet

CECTION 4



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: Id	entification of th	e substance/mixture and of the company/undertaking	
1.1. Produ	ct identifier		
Product name:	CYTOMEGALOVIRUS	ELISA IgG	
Product code:	G1004		
Product form:	Mixture		
Trade name:	ELISA Kit		
1.2. Releva	ant identified uses of	the substance or mixture and uses advised against	
1.2.1. Relevant i	dentified uses		
Professional use	specifications:	For professional use only	
Use of the substa	ince/mixture:	In Vitro Diagnostic use	
1.2.2. Uses advised against			
No additional info	ormation 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	Kit Configuration		
	According to regulations (EC) no. 1272/2008 [CLP]			
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

# Safety Data Sheet

According to Regulation (EU) 2015/830



This SDS costion refers evaluation	
This SDS section refers exclusiv	
	n of the substance/mixture and of the company/undertaking
1.1. Product identifier	
Product name: CYTOMEGAI	LOVIRUS ELISA IgG
Product code: G1004	
Product form: Mixture	
	rcell Stop Reagent)
	uses of the substance or mixture and uses advised against
1.2.1. Relevant identified	
Professional use specifications:	
Use of the substance/mixture:	In vitro Diagnostic use
<b>1.2.2. Uses advised against</b> No additional information avail	lahla
No additional information avail	lable
	lier of the safety data sheet
VIRCELL, S.L.	
Parque Tecnológico de la Salud 18016 Granada - Spain	i, Avicena 8
T +34 958 441264 - F +34 9585	10712
customerservice@vircell.com	
1.4. Emergency telepho	ne number
	nour service) – applicable to EU countries only
SECTION 2: Hazards iden	htification
2.1. Classification of the subs	
	gulation (EC) No. 1272/2008 [CLP]
Skin corrosion/irritation Cat	tegory 1A H314
Full text of H statements : see	section 16.
Adverse physicochemical, hun	nan health and environmental effects
No additional information avail	
2.2. Label elements	
Labelling According to Regulat	tion (EC) No. 1272/2008 [CLP]
Hazard pictograms (CLP):	
	PG
	GHS05
Signal word (CLP):	Danger
Hazard statements (CLP):	H314 - Causes severe skin burns and eye damage
Precautionary statements	P280 - Wear eye protection, face protection, protective clothing, protective gloves
(CLP):	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

### 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

P363 - Wash contaminated clothing before reuse

# SECTION 3: Composition/information on ingredients

# 3.1. Substance

Not applicable



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Name	Product identifier	%	Classification According to Regulation (EC) No. 1272/2008 [CLP]
Sulfuric acid Specific concentration limit	(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
Name	Product identifier	Specifi	c 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 measur	res
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	ubstance 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 resp Protective equipment: Emergency procedures:	Wear suitable protective clothing, gloves and eye/face protection. Avoid breathing dust/fume/gas/mist/vapours/spray	
6.2. Environmental preca	autions	

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

According to Regulation (EU) 2015/830



# 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 Keep container tightly closed. Store in a well-ventilated place. Keep cool Storage conditions: 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	I-93-9)	
EU	IOELV TWA (mg/m³)	0,05 mg/m <sup>3</sup> (taking into account potential limitations and interferences which take place in the presence of other Sulphur compounds-mist)
Austria	MAK (mg/m <sup>3</sup> )	0,1 mg/m <sup>3</sup> (corresponds to 0.05 mg/m <sup>3</sup> Thoracic-inhalable fraction)
Austria	MAK Short time value (mg/m <sup>3</sup> )	0,2 mg/m <sup>3</sup> (inhalable fraction)
Belgium	Limit value (mg/m <sup>3</sup> )	0,2 mg/m <sup>3</sup>
Bulgaria	OEL TWA (mg/m³)	0,05 mg/m <sup>3</sup> (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 <sup>3</sup> )	0,05 mg/m <sup>3</sup>
Cyprus	OEL TWA (mg/m³)	0,05 mg/m <sup>3</sup> (vapor)
Czech Republic	Expoziční limity (PEL) (mg/m <sup>3</sup> )	1 mg/m <sup>3</sup> 0,05 mg/m <sup>3</sup> (concentrated-mist)
Denmark	Grænseværdie (langvarig) (mg/m <sup>3</sup> )	0,05 mg/m <sup>3</sup> (thoracic fraction-mist)
Estonia	OEL TWA (mg/m³)	1 mg/m³ (fume)
Finland	HTP-arvo (8h) (mg/m³)	0,05 mg/m <sup>3</sup>
Finland	HTP-arvo (15 min)	0,1 mg/m <sup>3</sup>
France	VME (mg/m <sup>3</sup> )	0,05 mg/m <sup>3</sup> (thoracic fraction)
France	VLE (mg/m <sup>3</sup> )	3 mg/m <sup>3</sup>
Germany	TRGS 900 Occupational exposure limit value (mg/m <sup>3</sup> )	0,1 mg/m <sup>3</sup> (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 <sup>3</sup> (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 <sup>3</sup> (mist)
Hungary	AK-érték	0,05 mg/m <sup>3</sup>
Ireland	OEL (8 hours ref) (ppm)	0,05 ppm



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

# 8.2. Exposure controls

Appropriate engineering controls: Provide adequate ventilation

Personal protective equipment:

Gloves. Protective goggles. Protective clothing

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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

1. Information on basic physical and chem	ical 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

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°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	

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SECTION 11: Toxicological information	
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 Not classified
Germ cell mutagenicity:	Not classified
Carcinogenicity:	Not classified
Reproductive toxicity:	
Specific target organ toxicity (single exposure):	Not classified
Specific target organ toxicity (repeated exposure):	
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	
The substance/mixture does not meet the PBT crite	-
The substance/mixture does not meet the PBT crite The substance/mixture does not meet the vPvB crit 12.6. Other adverse effects	-
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The substance/mixture does not meet the PBT crite The substance/mixture does not meet the vPvB crite <b>12.6. Other adverse effects</b> No additional information available <b>SECTION 13: Disposal considerations</b> <b>13.1. Waste treatment methods</b> Waste treatment methods: Product/Packaging disposal recommendations: <b>SECTION 14: Transport information</b> In accordance with ADR / RID / IMDG / IATA / AND <b>14.1. UN number</b> UN-No. (ADR): UN-No. (IMDG): UN-No. (IATA): UN-No. (IATA): UN-No. (RID): <b>14.2. UN proper shipping name</b> Proper Shipping Name (IMDG):	eria of REACH regulation, annex XIII Consult the appropriate local waste disposal expert about waste disposal Handle uncleaned empty containers as full ones 2796 2796 2796 2796 2796 2796 2796 2796
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The substance/mixture does not meet the PBT crite The substance/mixture does not meet the vPvB crite <b>12.6. Other adverse effects</b> No additional information available <b>SECTION 13: Disposal considerations</b> <b>13.1. Waste treatment methods</b> Waste treatment methods: Product/Packaging disposal recommendations: <b>SECTION 14: Transport information</b> In accordance with ADR / RID / IMDG / IATA / AND <b>14.1. UN number</b> UN-No. (ADR): UN-No. (IMDG): UN-No. (IMDG): UN-No. (IATA): UN-No. (RID): <b>14.2. UN proper shipping name</b> Proper Shipping Name (IMDG): Proper Shipping Name (IATA): Proper Shipping Name (IATA): Proper Shipping Name (ADN):	eria of REACH regulation, annex XIII Consult the appropriate local waste disposal expert about waste disposal Handle uncleaned empty containers as full ones 2796 2796 2796 2796 2796 2796 2796 2796
The substance/mixture does not meet the PBT crite The substance/mixture does not meet the vPvB crite <b>12.6. Other adverse effects</b> No additional information available <b>SECTION 13: Disposal considerations</b> <b>13.1. Waste treatment methods</b> Waste treatment methods: Product/Packaging disposal recommendations: <b>SECTION 14: Transport information</b> In accordance with ADR / RID / IMDG / IATA / AND <b>14.1. UN number</b> UN-No. (ADR): UN-No. (IMDG): UN-No. (IMDG): UN-No. (IATA): UN-No. (RID): <b>14.2. UN proper shipping name</b> Proper Shipping Name (IMDG): Proper Shipping Name (IATA):	eria of REACH regulation, annex XIII Consult the appropriate local waste disposal expert about waste disposal Handle uncleaned empty containers as full ones 2796 2796 2796 2796 2796 2796 2796 2796

# Safety Data Sheet

According to Regulation (EU) 2015/830



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
	A.
	8
IMDG	
Transport hazard class(es) (IMDG):	8
Danger labels (IMDG):	8
	<u>^</u>
	8
ΙΑΤΑ	
Transport hazard class(es) (IATA):	8
Hazard labels (IATA):	8
	8
ADN	
Transport hazard class(es) (ADN):	8
Danger labels (ADN):	8
	8
RID	
Transport hazard class(es) (RID):	8
Danger labels (RID):	8
	8
	· ·

Safety Data Sheet

According to Regulation (EU) 2015/830



14.4.	Packing group	
	g group (ADR):	II
	g group (IMDG):	II
	g group (IATA):	I
	g group (ADN):	I
Packin	g group (RID):	I
14.5.	Environmental hazards	
Dange	rous for the environment:	No
Marine	e pollutant:	No
Other	information:	No supplementary information available
14.6.	Special precautions for user	
- Over	land transport	
	ication code (ADR) :	C1
	d quantities (ADR):	1
	ed quantities (ADR):	E2
-	g instructions (ADR):	P001, IBC02
	packing provisions (ADR):	MP15
	le tank and bulk container instructions (ADR):	T8
	le tank and bulk container special provisions	TP2
	ode (ADR):	L4BN
	e for tank carriage:	AT
	oort category (ADR):	2
	d identification number (Kemler No.):	80
Orang	e plates:	<b>80</b> <b>2796</b>
Tunne	l restriction code (ADR):	E
EAC co	ode:	2R
- Trans	sport by sea	
	d quantities (IMDG):	1L
	red quantities (IMDG):	E2
	g instructions (IMDG):	 P001
	cking instructions (IMDG):	IBC02
-	ecial provisions (IMDG):	B20
-	nstructions (IMDG):	T8
	pecial provisions (IMDG):	TP2
	lo. (Fire):	F-A
	lo. (Spillage):	S-B
	ge category (IMDG):	В
	ties and observations (IMDG):	Colourless liquid, mixture not exceeding 1.405 relative density. Highly corrosive to most metals. Cause burns to skin, eyes and mucous membranes
- Air tr	ransport	
	ccepted quantities (IATA):	E2
	mited quantities (IATA):	Y840

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

# Safety Data Sheet

According to Regulation (EU) 2015/830



CAO max net quantity (IATA):	30L	
ERG code (IATA):	8L	
- Inland waterway transport		
• •	64	
Classification code (ADN) :	C1	
Limited quantities (ADN):	1 L	
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):	Т8	
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. 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	se the product
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### 15.2. Chemical safety assessment

No additional information available



Safety Data Sheet According to Regulation (EU) 2015/830

# 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
РВТ	Persistent Bioaccumulative Toxic
CAS	Chemical Abstracts Service
CSR	Chemical Safety Report
Other inform	ation: 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 EL	JH-statements:			
Skin Corr. 1A Skin corrosion/irritation Category 1A				
H314 Causes severe skin burns and eye damage				
Classification Accor	rding to Regulation (EC) Nr. 1272/2008	Classification procedure		
Skin corrosion/irrita	ation, 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



According to Regulation (EU) 2015/830

	In 1: Identification of the substance	e/mixture and of the company/undertaking		
1.	Product identifier			
Produ	ct name:	CYTOMEGALOVIRUS ELISA IgG		
Produ	ct code:	G1004		
Produ	ct form:	Mixture		
Trade	name:	ELISA Kit (Vircell Wash Buffer)		
1.2. Relevant identified uses of the substance or mixture and uses advised against				
.2.1.	Relevant identified uses			
Profes	sional use specifications:	For professional use only		
Use of	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 s	sheet		
•	e Tecnológico de la Salud, Avicena 8			
	Granada - Spain 958-44 12 64 - F +34 958-51 07 12			
	nerservice@vircell.com			
L <b>.4.</b>	Emergency telephone number			
	ency number:	112 (24 hour service) – applicable to EU countries only		
- 0	,			
SECTIO	ON 2: Hazards identification			
2.1.	Classification of the substance or mixture			
Classific	ation According to Regulation (EC) No. 1272	/2008 [CLP]		
Skin se	ensitisation, Category 1	H317		
ull text	of H statements: see section 16			
Adverse	physicochemical, human health and enviro	nmental effects:		
No addi	tional information available			
2.2.	Label elements			
abellin	g According to Regulation (EC) No. 1272/200	18 [CLP]		
Hazar	d pictograms (CLP):	GHS07		
	word (CLP):	Warning		
Signal	laus ingradiants.	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),		
	dous ingredients:	150tha201-5-0he [LC 110. 220-235-0] (3.1),		
Hazar	d statements (CLP):	H317 - May cause an allergic 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

# CYTOMEGALOVIRUS ELISA IgG Vircell Wash buffer

Safety Data Sheet According to Regulation (EU) 2015/830





# 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 &gt;= 0.6) Skin Corr. 1B, H314</c></c>

# Full text of H-statements: see section 16

SECTIO	ON 4: First aid measures		
4.1.	Description of first aid measures	מזווי	
First-aid measures general: Never give anyth		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	
		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 imme		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 rinsing. Seek medical attention if ill effect or irritation develops		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	
<b>u</b>		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.	.2. Most important symptoms and effects, both acute and delayed		
Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal		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		e medical attention and special treatment needed	
Treat symptomatically			
SECTIO	ON 5: Firefighting measur	es	
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 substance or mixture	
Fire ha	azard:	No data available	
Explosion hazard:		No data available	

Evacuate the personnel away from the fumes

Avoid fire-fighting water from entering environment

Extra personal protection: complete protective clothing including self-contained breathing apparatus

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.

Other information:

01/06/2018

Precautionary measures fire:

Hazardous decomposition products in case of fire:

Advice for firefighters

Protective equipment for firefighters:

5.3.

No data available

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			
Protec	tive equipment :	Wear suitable protective clothing, gloves and eye/face protection. Avoid breathing dust/fume/gas/mist/vapours/spray		
Emerg	ency procedures:	Evacuate unnecessary personnel. Ensure adequate ventilation		
6.2.	Environmental precautions			
Avoid re	elease to the environment. Prevent entry to	sewers and public waters		
6.3.	Methods and material for containment	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		
64	Reference to other sections			

#### 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, 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)	

#### 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



# CYTOMEGALOVIRUS ELISA IgG Vircell Wash buffer

Safety Data Sheet

According to Regulation (EU) 2015/830



SECTION 9: Physical and chemical properties	
9.1. Information on basic physical and chemical p	
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	v and reactivity
32011011 201 3tubilit	

**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

According to Regulation (EU) 2015/830



Respi	ratory or skin sensitisation :	May cause an allergic skin re	action		
Germ cell mutagenicity:		Not classified	Not classified		
Carcinogenicity:		Not classified	Not classified		
Repro	ductive toxicity:	Not classified			
STOT-	single exposure:	Not classified			
STOT-	repeated exposure:	Not classified			
Aspira	ation hazard:	Not classified			
SECTI	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	a available				
12.4.	Mobility in soil				
No add	itional information available				
12.5.	Results of PBT and vPvB assessment				
The sub	ostance/mixture does not meet the PBT criteria	of REACH regulation, annex XIII			
The sub	ostance/mixture does not meet the vPvB criteri	a of REACH regulation, annex XII			
12.6.	Other adverse effects				
No add	itional information available				
SECTI	ON 13: Disposal considerations				
13.1.	Waste treatment methods				
Waste	e treatment methods:	Consult the appropriate loo	al waste disposal expert abour	t waste disposal	
Produ	ct/Packaging disposal recommendations:	Handle uncleaned empty c	ontainers as full ones		
SECTI	ON 14: Transport information				
In acco	rdance with ADN / ADR / IATA / IMDG / RID				
	IMDC			DID	

ADR	IMDG	ΙΑΤΑ	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 cl	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

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 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**

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



# CYTOMEGALOVIRUS ELISA IgG Vircell Wash buffer



Safety Data Sheet

According to Regulation (EU) 2015/830

Full text of H- and EUH-statements:				
Acute Tox. 3 (Dermal)	Acute toxicity (de	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 swallowe	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	Toxic if inhaled		
H400 Very toxic to aquatic life		atic 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