

**Trade name:** HISCL SARS-CoV-2 S-IgG Calibrator**Current version :** 1.0.1, issued: 04.05.2022**Replaced version:** 1.0.0, issued: 11.08.2021**Region:** IE**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name****HISCL SARS-CoV-2 S-IgG Calibrator****1.2 Relevant identified uses of the substance or mixture and uses advised against****Relevant identified uses of the substance or mixture**

For in-vitro diagnosis

**Uses advised against**

No data available.

**1.3 Details of the supplier of the safety data sheet****Address**

SYSMEX LTD

Sysmex House

Garamonde Drive

Wymbush

Milton Keynes

Buckinghamshire

United Kingdom

MK8 8DF

Telephone no. +44 (0)333 320 3460

Fax no. +44 (0)1908 267 901

**Advice on Safety Data Sheet**

info@sysmex-europe.com

**1.4 Emergency telephone number**

For medical advice:

+353 1 809 2166 (National Poisons Information Centre)

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification information**

This product is assessed and classified using the methods and criteria below referred to in Article 9 of Regulation (EC) n° 1272/2008:

Physical hazards: determined through assessment data based on the methods or standards referred to in part 2 of Annex I to CLP

Health hazards and environmental hazards: determined through toxicological and ecotoxicological assessment data based on the methods or standards referred to in Part 3, 4 and 5 of Annex I to CLP.

This product does not meet the classification criteria given in the Regulation (EC) No 1272/2008 (CLP).

**2.2 Label elements****Labelling according to Regulation (EC) No 1272/2008 (CLP Regulation)****Hazard pictograms**

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**Signal word**

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**Hazard statement(s)**

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**Hazard statements (EU)**

EUH208

Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

EUH210

Safety data sheet available on request.

**Precautionary statement(s)**

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**Labelling information**

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The labelling (EU hazard statements) meets the criteria of annex II of Directive (EC) Nr. 1272/2008 (CLP).

**2.3 Other hazards**

PBT assessment  
No data available.

vPvB assessment  
No data available.

**SECTION 3: Composition/information on ingredients****3.1 Substances**

Not applicable. The product is not a substance.

**3.2 Mixtures****Hazardous ingredients**

No	Substance name	Additional information	
	CAS / EC / Index / REACH no	Classification (EC) 1272/2008 (CLP)	Concentration
			%
1	<b>1,2-benzisothiazol-3(2H)-one</b>		
	2634-33-5 220-120-9 613-088-00-6 -	Acute Tox. 4*; H302 Aquatic Acute 1; H400 Eye Dam. 1; H318 Skin Irrit. 2; H315 Skin Sens. 1; H317	< 0,05 wt%

Full Text for all H-phrases and EUH-phrases: pls. see section 16

(\* , \*\* , \*\*\* , \*\*\*\*) Detailed explanation pls. refer to CLP regulation No. 1272/2008, annex VI, 1.2

No	Note	Specific concentration limits	M-factor (acute)	M-factor (chronic)
1	-	Skin Sens. 1; H317: C ≥ 0,05%	-	-

**SECTION 4: First aid measures****4.1 Description of first aid measures****General information**

In case of persisting adverse effects, consult a physician. Remove contaminated clothing and shoes immediately, and launder thoroughly before reusing.

**After inhalation**

Remove affected person from the immediate area. Ensure supply of fresh air.

**After skin contact**

Wash off immediately with soap and water.

**After eye contact**

Separate eyelids, wash the eyes thoroughly with water (15 min.).

**After ingestion**

Call a doctor immediately. Do not induce vomiting. Never give anything by mouth to an unconscious person.

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

No data available.

**4.3 Indication of any immediate medical attention and special treatment needed**

No data available.

**SECTION 5: Firefighting measures****5.1 Extinguishing media****Suitable extinguishing media**

Water spray jet

**Unsuitable extinguishing media**

High power water jet

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In the event of fire, the following can be released: Carbon dioxide (CO<sub>2</sub>); Carbon monoxide (CO)

**5.3 Advice for firefighters**

Use self-contained breathing apparatus. Wear protective clothing.

**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures****For non-emergency personnel**

Refer to protective measures listed in sections 7 and 8. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Do not inhale vapours.

**For emergency responders**

Personal protective equipment (PPE) - see section 8.

**6.2 Environmental precautions**

Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil.

**6.3 Methods and material for containment and cleaning up**

Contain and collect spillage with non-combustible absorbent materials, e.g. sand, earth, vermiculite, diatomaceous earth and place in container for disposal according to local regulations (see section 13).

**6.4 Reference to other sections**

Information regarding safe handling, see section 7. Information regarding personal protective measures, see section 8. Information regarding waste disposal, see section 13.

**SECTION 7: Handling and storage****7.1 Precautions for safe handling****Advice on safe handling**

Risks inherent to handling the product must be minimised by applying the appropriate protective and preventive measures. Working processes should - so far as possible, according to the state of the art - be designed to rule out bodily contact or the release of hazardous substances.

**General protective and hygiene measures**

Do not eat, drink or smoke during work time. Keep away from food, drink and animal feeding stuffs. Wash hands and skin before breaks and after work. Do not inhale vapours. Avoid contact with eyes and skin. Remove soiled or soaked clothing immediately.

**Advice on protection against fire and explosion**

No special measures necessary.

**7.2 Conditions for safe storage, including any incompatibilities****Technical measures and storage conditions**

Keep container tightly closed in a cool, well-ventilated place.

**Requirements for storage rooms and vessels**

Containers which are opened must be carefully closed and kept upright to prevent leakage.

**Incompatible products**

Do not store together with: oxidizing agents

**7.3 Specific end use(s)**

No data available.

**SECTION 8: Exposure controls/personal protection****8.1 Control parameters**

No parameters available for monitoring.

**8.2 Exposure controls****Appropriate engineering controls**

No data available.

**Personal protective equipment**

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If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn. In case of aerosol and mist formation, take appropriate measures for breathing protection in the event workplace threshold values are not specified.

**Eye / face protection**

Safety glasses (EN 166)

**Hand protection**

In case of intensive contact, wear protective gloves (EN 374). Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves.

**Other**

Normal chemical work clothing.

**Environmental exposure controls**

No data available.

**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

<b>State of aggregation</b>	
liquid	
<b>Form/Colour</b>	
Liquid	
Colorless to light yellow	
<b>Odour</b>	
odourless	
<b>pH value</b>	
Value	6,95 - 7,05
<b>Boiling point / boiling range</b>	
No data available	
<b>Melting point/freezing point</b>	
No data available	
<b>Decomposition temperature</b>	
No data available	
<b>Flash point</b>	
No data available	
<b>Ignition temperature</b>	
No data available	
<b>Flammability</b>	
No data available	
<b>Lower explosion limit</b>	
No data available	
<b>Upper explosion limit</b>	
No data available	
<b>Vapour pressure</b>	
No data available	
<b>Relative vapour density</b>	
No data available	
<b>Relative density</b>	
No data available	

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<b>Density</b>	
No data available	
<b>Solubility in water</b>	
Comments	soluble
<b>Solubility</b>	
No data available	
<b>Partition coefficient n-octanol/water (log value)</b>	
No data available	
<b>Kinematic viscosity</b>	
No data available	
<b>Particle characteristics</b>	
No data available	

**9.2 Other information**

<b>Other information</b>	
No data available.	

**SECTION 10: Stability and reactivity****10.1 Reactivity**

Dangerous reactions are not expected if the product is handled according to its intended use.

**10.2 Chemical stability**

Stable under recommended storage and handling conditions (See section 7).

**10.3 Possibility of hazardous reactions**

None, when used as directed.

**10.4 Conditions to avoid**

None, if handled according to intended use.

**10.5 Incompatible materials**

No data available.

**10.6 Hazardous decomposition products**

None, if handled according to intended use.

**SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

<b>Acute oral toxicity</b>	
No data available	
<b>Acute dermal toxicity</b>	
No data available	
<b>Acute inhalational toxicity</b>	
No data available	
<b>Skin corrosion/irritation</b>	
No data available	
<b>Serious eye damage/irritation</b>	
No data available	
<b>Respiratory or skin sensitisation</b>	
No data available	
<b>Germ cell mutagenicity</b>	
No data available	
<b>Reproduction toxicity</b>	

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No data available

**Carcinogenicity**

No data available

**STOT - single exposure**

No data available

**STOT - repeated exposure**

No data available

**Aspiration hazard**

No data available

**11.2 Information on other hazards****Endocrine disrupting properties**

No data available.

**Other information**

No data available.

**SECTION 12: Ecological information****12.1 Toxicity****Toxicity to fish (acute)**

No data available

**Toxicity to fish (chronic)**

No data available

**Toxicity to Daphnia (acute)**

No data available

**Toxicity to Daphnia (chronic)**

No data available

**Toxicity to algae (acute)**

No data available

**Toxicity to algae (chronic)**

No data available

**Bacteria 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 data available.

**12.5 Results of PBT and vPvB assessment****Results of PBT and vPvB assessment**

PBT assessment

No data available.

vPvB assessment

No data available.

**12.6 Endocrine disrupting properties**

No data available.

**12.7 Other adverse effects**

No data available.

**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

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Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

**Packaging**

Residues must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

**SECTION 14: Transport information****14.1 Transport ADR/RID/ADN**

The product is not subject to ADR/RID/ADN regulations.

**14.2 Transport IMDG**

The product is not subject to IMDG regulations.

**14.3 Transport ICAO-TI / IATA**

The product is not subject to ICAO-TI / IATA regulations.

**14.4 Other information**

No data available.

**14.5 Environmental hazards**

Information on environmental hazards, if relevant, please see 14.1 - 14.3.

**14.6 Special precautions for user**

No data available.

**14.7 Maritime transport in bulk according to IMO instruments**

Not relevant

**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
**EU regulations****Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation)**

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances considered as substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

**REACH candidate list of substances of very high concern (SVHC) for authorisation**

According to available data and the information provided by preliminary suppliers, the product does not contain substances that are considered substances meeting the criteria for inclusion in annex XIV (List of Substances Subject to Authorisation) as laid down in Article 57 and article 59 of REACH (EC) 1907/2006.

**Regulation (EC) No 1907/2006 (REACH) Annex XVII: RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES**

The product contains following substance(s) that are considered being subject to REACH regulation (EC) 1907/2006 annex XVII.

No	Substance name	CAS no.	EC no.	No
1	1,2-benzisothiazol-3(2H)-one	2634-33-5	220-120-9	75
2	sodium hydroxide	1310-73-2	215-185-5	75

**Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances**

This product is not subject to Part 1 or 2 of Annex I.

**Other regulations**

Adhere to the national sanitary and occupational safety regulations when using this product.

**15.2 Chemical safety assessment**

A chemical safety assessment has not been carried out for this mixture.

**SECTION 16: Other information**

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**Sources of key data used to compile the data sheet:**

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

Directives 2000/39/EC, 2006/15/EC, 2009/161/EU, (EU) 2017/164.

National Threshold Limit Values of the corresponding countries as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding section.

**Full text of the H- and EUH- phrases drawn up in sections 2 and 3 (provided not already drawn up in these sections)**

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.

**Creation of the safety data sheet**

UMCO GmbH - D-21107 Hamburg, Georg-Wilhelm-Strasse 187, Tel.: +49(40)555 546 300, Fax: +49(40)555 546 357, e-mail: [umco@umco.de](mailto:umco@umco.de)

This information is based on our present knowledge and experience.

The safety data sheet describes products with a view to safety requirements.

It does not however, constitute a guarantee for any specific product properties and shall not establish a legally valid contractual relationship.

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