

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:** GB**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

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Wymbush

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MK8 8DF

Telephone no. +44 (0)333 320 3460

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Advice on Safety Data Sheet

info@sysmex-europe.com

1.4 Emergency telephone number

For medical advice (in German and English):

+49 (0)551 192 40 (Giftinformationszentrum Nord)

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

-

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	1,2-benzisothiazol-3(2H)-one		
	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 (CO₂); 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**

State of aggregation	
liquid	
Form/Colour	
Liquid	
Colorless to light yellow	
Odour	
odourless	
pH value	
Value	6.95 - 7.05
Boiling point / boiling range	
No data available	
Melting point/freezing point	
No data available	
Decomposition temperature	
No data available	
Flash point	
No data available	
Ignition temperature	
No data available	
Flammability	
No data available	
Lower explosion limit	
No data available	
Upper explosion limit	
No data available	
Vapour pressure	
No data available	
Relative vapour density	
No data available	
Relative density	
No data available	

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

9.2 Other information

Other information	
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**

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

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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

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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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Prod-ID 778685