

**Trade name:** HISCL™ SARS-CoV-2 Ag Assay Kit (R2 reagent)**Current version :** 1.0.2, issued: 07.05.2025**Replaced version:** 1.0.1, issued: 04.05.2022**Region:** IE**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Trade name

**HISCL™ SARS-CoV-2 Ag Assay Kit (R2 reagent)****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 does not meet the classification and labelling criteria given in the Regulation (EC) No 1272/2008 (CLP).

**2.2 Label elements**

Not relevant

**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	sodium azide		
	26628-22-8 247-852-1 011-004-00-7 -	Acute Tox. 2*; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032	< 0,50 wt%

Full text of H- and EUH-phrases, if not already mentioned in section 2.2: see section 16.

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

**Acute toxicity estimate (ATE) values**

No	oral	dermal	inhalative
1	27 mg/kg bodyweight		

**SECTION 4: First aid measures**

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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

**5.2 Special hazards arising from the substance or mixture**

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**

Take up with absorbent material (e.g., sand, kieselguhr, universal binder). When collected, handle material as described under the section heading "Disposal considerations".

**6.4 Reference to other sections**

No data available.

**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.

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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****Occupational exposure limit values**

No	Substance name	CAS no.	EC no.
1	sodium azide	26628-22-8	247-852-1
	2000/39/EC		
	Sodium azide		
	WEL short-term (15 min reference period)	0,3	mg/m <sup>3</sup>
	WEL long-term (8-hr TWA reference period)	0,1	mg/m <sup>3</sup>
	Skin resorption / sensibilisation	Skin	
	<b>List of Chemical Agents and Occupational Exposure Limit Values (Code of Practice)</b>		
	Sodium azide (as NaN <sub>3</sub> )		
	WEL short-term (15 min reference period)	0,3	mg/m <sup>3</sup>
	WEL long-term (8-hr TWA reference period)	0,1	mg/m <sup>3</sup>
	Comments	IOELV, Skin	

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

No data available.

**Personal protective equipment****Respiratory protection**

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</b>	
Suspension	
<b>Colour</b>	
brown	
<b>Odour</b>	
odourless	
<b>pH value</b>	
Value	6,5
<b>Boiling point / boiling range</b>	
No data available	
<b>Melting point/freezing point</b>	
No data available	
<b>Decomposition temperature</b>	

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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
<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 (result of the ATE calculation for the mixture)</b>
<b>Product Name</b>
HISCL™ SARS-CoV-2 Ag Assay Kit (R2 reagent)

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Comments	The result of the applied calculation method according to the European Regulation (EC) 1272/2008 (CLP), Paragraph 3.1.3.6, Part 3 of Annex I is outside the values that imply a classification / labelling of this mixture according to table 3.1.1 defining the respective categories (ATE oral > 2000 mg/kg).
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Acute oral toxicity			
No	Substance name	CAS no.	EC no.
1	sodium azide	26628-22-8	247-852-1
LD50		27	mg/kg bodyweight
Species	rat		
Source	RTECS		

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
No data available

Carcinogenicity
No data available

STOT - single exposure
No data available

STOT - repeated exposure
No data available

Aspiration hazard
No data available

Endocrine disrupting properties
No data available

**11.2 Information on other hazards**

**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.

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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	
Product Name	
HISCL™ SARS-CoV-2 Ag Assay Kit (R2 reagent)	
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****Product**

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 UN number or ID number**

Not classified as dangerous in the meaning of transport regulations.

**14.2 UN proper shipping name**

Not classified as dangerous in the meaning of transport regulations.

**14.3 Transport hazard class(es)**

Not classified as dangerous in the meaning of transport regulations.

**14.4 Packing group**

Not classified as dangerous in the meaning of transport regulations.

**14.5 Environmental hazards**

Not classified as dangerous in the meaning of transport regulations.

**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	magnesium-chloride-hexahydrate	7791-18-6	232-094-6
75			
Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances			

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This product is not subject to Part 1 or 2 of Annex I.
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<b>Other regulations</b>
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Adhere to the national sanitary and occupational safety regulations when using this product.
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**15.2 Chemical safety assessment**

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

**SECTION 16: Other information****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)**

EUH032

Contact with acids liberates very toxic gas.

H300

Fatal if swallowed.

H400

Very toxic to aquatic life.

H410

Very toxic to aquatic life with long lasting effects.

**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.

Alterations/supplements:

Alterations to the previous edition are marked in the left-hand margin.

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