

Trade name: HISCL β -Amyloid 1-42 Assay Kit Calibrator**Current version :** 2.0.0, issued: 27.06.2024**Replaced version:** 1.0.0, issued: 23.08.2023**Region:** IE**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name****HISCL β -Amyloid 1-42 Assay Kit 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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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 in accordance with Regulation (EC) No 1272/2008 (CLP)**

Aquatic Chronic 2; H411

Eye Irrit. 2; H319

Skin Irrit. 2; H315

Skin Sens. 1; H317

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.

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

GHS07



GHS09

Signal word

Warning

Hazardous component(s) to be indicated on label:

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3-one (3:1)

Hazard statement(s)

H315

Causes skin irritation.

H317

May cause an allergic skin reaction.

H319

Causes serious eye irritation.

H411

Toxic to aquatic life with long lasting effects.

Precautionary statement(s)

P273

Avoid release to the environment.

P280

Wear protective gloves/protective clothing/eye protection/face protection.

P391

Collect spillage.

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PBT assessment

According to the information provided in the supply chain, the mixture does not contain > 0.1% of a substance that is considered to be PBT.

vPvB assessment

According to the information provided in the supply chain, the mixture does not contain > 0.1% of a substance that is considered to be vPvB.

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	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H - isothiazol-3-one (3:1)		
	55965-84-9 - 613-167-00-5 -	Acute Tox. 2; H310 Acute Tox. 2; H330 Acute Tox. 3; H301 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH071 Eye Dam. 1; H318 Skin Corr. 1C; H314 Skin Sens. 1A; H317	>= 0,06 - < 0,25 wt%

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

No	Note	Specific concentration limits	M-factor (acute)	M-factor (chronic)
1	B	Skin Sens. 1A; H317: C >= 0,0015% Eye Irrit. 2; H319: C >= 0,06% Skin Irrit. 2; H315: C >= 0,06% Skin Corr. 1C; H314: C >= 0,6% Eye Dam. 1; H318: C >= 0,6%	M = 100	M = 100

Full text for the notes: pls. see section 16 "Notes relating to the identification, classification and labelling of substances ((EC) No 1272/2008, Annex VI)".

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

Remove contaminated clothing and shoes and launder thoroughly before reusing. In case of persisting adverse effects, consult a physician. In case of allergic symptoms, especially respiratory tract related, seek medical help immediately.

After inhalation

Ensure supply of fresh air.

After skin contact

Instantly wash with copious amounts of water. Consult a doctor if skin irritation persists.

After eye contact

Remove contact lenses. Rinse eye thoroughly under running water keeping eyelids wide open and protecting the unaffected eye (at least 10 to 15 minutes).

After ingestion

Rinse the mouth thoroughly with water. 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

Treat symptomatically

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

Water spray jet; Carbon dioxide; Extinguishing powder; Alcohol-resistant foam

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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 (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.

For emergency responders

Personal protective equipment (PPE) - see section 8.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Collect mechanically. When collected, handle material as described under the section heading "Disposal considerations".

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

General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from foodstuffs and beverages. Wash hands before breaks and after work. Do not inhale dust.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

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

Requirements for storage rooms and vessels

Containers which are opened must be carefully resealed and kept upright to prevent leakage. Always keep in containers of same material as the original.

Incompatible products

Substances to be avoided, see section 10.

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

Ensure adequate ventilation, local exhaust at the work station if necessary.

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 dust formation, take appropriate measures for breathing protection in the event that 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

Chemical-resistant work clothes.

Environmental exposure controls

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No data available.

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

State of aggregation			
solid			
Form			
Powder			
Colour			
colourless to pale yellow			
Odour			
odourless			
pH value			
Value		7,0	
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			
Density			
No data available			
Solubility in water			
Value		100	%
Reference temperature		25	°C
Comments		completely 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**

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No data available.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Dangerous reactions are not to be expected when handling product according to its intended use.

10.4 Conditions to avoid

Extreme heat

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition productsIn case of fire the following can be released: Carbon dioxide (CO₂); Carbon monoxide (CO)**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

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

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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

According to the information provided in the supply chain, the mixture does not contain > 0.1% of a substance that is considered to be PBT.

vPvB assessment

According to the information provided in the supply chain, the mixture does not contain > 0.1% of a substance that is considered to be vPvB.

12.6 Endocrine disrupting properties

No data available.

12.7 Other adverse effects

No data available.

12.8 Other information**Other information**

Do not discharge product unmonitored into the environment.

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

Disposal of the product should be carried out in accordance with all applicable regulations following consultation with the responsible local authority and the disposal company in an authorised and suitable disposal facility.

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**

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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	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	55965-84-9	-	75
Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances				
This product is subject to Part I of Annex I, risk category:			E2	

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)

EUH071	Corrosive to the respiratory tract.
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Notes relating to the identification, classification and labelling of substances and mixtures ((EC) No 1272/2008, Annex VI)

B Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

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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Prod-ID 796557