1. Identification of the substance/mixture and of the company

1.1 Product identifier

1.1.1 Trade name: Milenia QuickLine HIT Control

1.1.2 Article number: MQCOHIT 1

1.1.3 Basic UDI-DI: 4260177041106M

1.2 Relevant identified uses of the substance or mixture and uses advised against

No data available

1.2.1 Application of the substance/the mixture

For in vitro diagnostic use only

1.3 Details of the supplier of the safety data sheet

Milenia Biotec GmbH
Versailler Str. 1
35394 Gießen
Germany
Tel.: +49 (0)641 948883 0
Fax: +49 (0)641 958883 80
info@milenia-biotec.de

1.4 Emergency telephone number:

Europe-wide emergency number: 112, available 24h, all calls to 112 are automatically routed to the local control centre.

2. Hazards identification

2.1 Classification according to Regulation (EC) No 1272/2008/GHS

No classification required

2.2 Label elements according to Regulation (EC) No 1272/2008/GHS

No label required

Additional Information:

EUH208 Contains mixture of 5-chloro-2-methyl-5-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1). May produce an allergic reaction.

2.3 Other hazards

no information required

3. Composition/information on ingredients

3.2 Mixtures

3.2.1 Description

Mixture of substances listed below with non-hazardous additions.

3.2.2 Dangerous components

Milenia QuickLine HIT Positive Control (MQHITC1)

Cas-No./EG No.:	Description	Concentration
26628-22-8/247-852-1	Sodium azide Acute Tox. 2, H300; Acute Tox. 1, H310; Acute Tox. 2, H330; STOT RE 2, H373; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; EUH032	< 0,1 %

Milenia QuickLine HIT Negative Control (MQHITC2)

Cas-No./EG No.:	Description	Concentration
55965-84-9/247-500-7 220-239-6	Mixture of 5-Chloro-2-methyl-3(2H)-isothiazolone (CIT) and 2-Methyl-3(2H)-isothiazolone (MIT) (3:1) Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330; Skin corrosion, 1C, H314; Skin Sens. 1A, H317; Eye damage 1, H318; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; EUH071 Specific concentration limits: Skin Corr. 1C; H314: C>= 0.6 % Skin Irrit. 2; H315: 0.06 % <=C < 0.6 % Eye Dam. 1; H318: C>= 0.6 % Eye Irrit. 2; H319: 0,06 % <=C < 0.6 % Skin Sens. 1A; H317: C >=0.0015 % M Factor: M=100 (acute), M=100 (chronic)	<0.0015%

Addition Information: No need for declaration below 0.1 %

4. First aid measures

Due to the low concentration of chemicals and the chromatographic nature of the assay personal damages are extremely unlikely if the test is done according to the instructions. So far no injuries have been reported that could be linked to the use of the lateral flow immunoassay. For safety reasons general First Aid measures for chemical substances will be listed nevertheless.

4.1 Description of first aid measures

General information: If irritation or signs of toxicity occur, seek medical attention

After inhalation: Remove source of exposure; supply fresh air

After skin contact: Remove source of exposure; wash affected area with water

After eye contact: Remove source of exposure; rinse opened eye for several minutes under running water

After swallowing: drink copious amounts of water

4.2 Most import symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:

CO_2, water spray, foam, dry chemical

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Protective equipment: No special measures required.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

Do not allow to enter waterways/soil. Absorb with absorbent material; dispose of contaminated material in accordance with Section 13.

6.3 Methods and material for containment and cleaning up:

Absorb liquid components with liquid-binding material.

6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment

See Section 13 for disposal information

7. Handling and storage

7.1 Precautions for safe handling: Keep away from food and beverages, wash hands before breaks and at the end of work. Avoid contact with the eyes and skin.

Information about fire – and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptables: No special requirements.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: None.

Maximum storage temperature: 8°C

Minimum storage temperature: 2°C

7.3 Specific end use(s) No further relevant information available.

8. Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

Not necessary

8.2 Exposure controls

Appropriate engineering controls No further data; see item 7.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

Keep away from food and beverages, wash hands before breaks and at the end of work. Avoid contact with the eyes and skin.

Respiratory protection: Not required.

Hand protection: Protective gloves

Material of gloves: As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked in the application.
Penetration time of glove material: The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
Eye/face protection: protective lab glasses.
Body protection: protective work clothing.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information:	MQHITC1 MQHITC2
Physical state:	lyophilisate
Colour:	colourless to slightly yellow
Odour:	odourless
Odour threshold:	not determined
Melting point/freezing point	not applicable
Boiling point or initial boiling point and boiling range:	not determined
Flammability:	not applicable
Lower and upper explosion limit	not applicable
Flash point:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not determined
Density	not determined
pH at 20°C:	~ 7
Viscosity	
Kinematic viscosity:	not determined
Dynamic:	not determined
Solubility Water:	soluble
Partition coefficient n-octonol/water (log value):	not determined
Vapour pressure:	not determined
Density and/or relative density:	not determined
9.2 Other information	No further relevant information available
Appearance Form:	lyophilisate
Important information on protection of health and environment, and on safety:	
Ignition temperature	not applicable
Explosive properties	product does not present an explosion hazard
Solvent content	not applicable
Organic solvents	0.0 %
Change in condition	void
Evaporation rate	not determined
Information with regard to physical hazard classes:	

Explosives	void
Flammable gases	void
Aerosols	void
Oxidising gases	void
Gases under pressure	void
Flammable liquids	void
Flammable solids	void
Self-reactive substances and mixtures	void
Pyrophoric liquids	void
Pyrophoric solids	void
Self-heating substances and mixtures	void
Substances and mixtures, which emit flammable gases in contact with water	void
Oxidising liquids	void
Oxidising solids	void
Organic peroxides	void
Corrosive to metals	void
Desensitised explosives	void

10. Stability and reactivity

10.1 Reactivity no data available

10.2 Chemical stability

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

No further relevant information available.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products:

Plastic Box: hazardous decomposition of products during burning possible

11. Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification

CAS: 55965-84-9, Mixture of 5-Chloro-2-methyl-3(2H)-isothiazolone (CIT) and 2-Methyl-3(2H)-isothiazolone (MIT) (3:1)

oral LD50: 53 mg/kg

CAS: 26628-22-8, sodium azide

Oral LD50: 27 mg/kg

Dermal LD50: 20 mg/kg

Skin corrosion/irritation No effect known.

Serious eye damage/irritation No effect known.

Respiratory or Skin sensitisation No irritant effect known.

Germ cell mutagenicity No effect known.

Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive toxicity Based on available data, the classification criteria are not met.

STOT-single exposure Based on available data, the classification criteria are not met.

STOT-repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

11.2 Information on other hazards

Endocrine disrupting properties None of the ingredients are included.

12. Ecological information

12.1 Toxicity

Aquatic 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 not applicable

12.6 Endocrine disrupting properties no data available

12.7 Other adverse effects

Additional ecological information: none

General notes:

In the concentrations at hand an environmental threat is not to be expected. The concentration of the substances in the reagent is so low that there is no need for declaration.

13. Disposal considerations

13.1 Waste treatment methods

Recommendation (Pos/neg Control Vial): Disposal must be made according to official local regulations. Potentially infectious material: AVV waste code 18 01 03 – Waste whose collection and disposal are subject to special requirements in order to prevent infections

Recommendation (empty packaging/Outer Box) Disposal must be made according to official local regulations. AVV waste code 15 01 05 - composite packaging

Recommendation (uncleaned packaging): Disposal must be made according to official local regulations. AVV waste code 15 01 10 - packaging containing residues of or contaminated by hazardous substances

Recommended cleansing agents: not applicable.

14. Transport information

14.1 UN number or ID number	
ADR, ADN, IMDG, IATA	void
14.2 UN proper shipping name	
ADR, ADN, IMDG, IATA	void
14.3 Transport hazard class(es)	
ADR, ADN, IMDG, IATA	void
14.4 Packaging group	
ADR, IMDG, IATA	void
14.5 Environmental hazards:	
Marine pollutant:	no
14.6 Special precautions for user	none
14.7 Maritime transport in bulk according to IMO instruments	not applicable
UN “Model Regulation”:	not applicable

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation (EU) 2019/1148

Annex I – Restricted Explosives Precursors None of the ingredients is listed.

Annex II – Reportable Explosives Precursors None of the ingredients is listed.

Annex XVII – Restrictions no restrictions known.

Annex XIV – Approval No ingredients listed.

SVHC/candidate list: No SVHC > 0.1% contained (according to current knowledge).

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out.

16. Other information

The given information is based on the current state of knowledge but does not guaranty product performances and cannot be used as basis for legal disputes. Milenia Biotec GmbH makes no warranties and assumes no liability in connection with the use of this information or in case of inappropriate handling of this product. Users should strictly respect the insert instructions. This is the user’s responsibility to determine the suitability of this information and to assure the adoption of necessary safety precautions.

Relevant phrases

H300 Fatal if swallowed.

H301 Toxic if swallowed.

H310 Fatal in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H330 Fatal if inhaled.

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Department issuing SDS: Quality Management

Abbreviations and acronyms:

ADR: European Agreement Concerning the International Carriage of Dangerous Goods

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very persistent and very Bioaccumulative

Acute Tox.: Acute toxicity

Skin Corr.: Skin corrosion

Skin Sens.: Skin sensitisation

Eye dam.: Eye damage

Eye irrit.: Eye irritation

Revision history

Date	Reason for change	Revision status
28.03.2022	New Document	A
02.10.2025	Addition to Annexes in chpt. 15, Addition of AVV waste codes in chpt. 13, Additional information in chpt. 11	B