

1. Identification of substance/mixture and contact

Trade name: Milenia® *QuickLine* HIT

Cat.-No. MQHIT 1 / MQHIT Z

Intended use: Lateral Flow Immunoassay for qualitative detection of IgG antibodies against PF4/polyanion-complexes

Manufacturer/supplier: Milenia Biotec GmbH
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Emergency Call: see your local poison information center!

2. Possible Hazards

Classification of substance/mixture: no single substances - kit is classified as a mixture

Declaration of hazards: no information necessary

Specific hazards: no information necessary

3. Composition/Information on components

Description: In-vitro-Diagnostic reagents

Ingredients of the kit:

- HIT Sample buffer (MQBHIT_2mL / MQBHITZ_0,5mL)
- HIT Test Unit (MQSHIT)

Identification of ingredients:

| CAS-Nr. | EG-Nr. | Description | component | Conc. | Indexing |
|------------|-----------|--------------|---------------|--------|----------|
| 54-64-8 | 200-201-4 | Thimerosal | MQSHIT | < 0,1% | -- |
| 26628-22-8 | 247-852-1 | Sodium azide | MQSHIT | < 0,1% | -- |
| 55965-84-9 | * | ProClin 300 | MQBHIT/MQHITZ | < 0,1% | -- |

* Proclin 300 is a mixture of substances where two of the components, 5-chloro-2-methyl-2H-isothiazol-3-one (EG-nr 247-500-7) and 2-methyl-2H-isothiazol-3-one (EG-nr 220-239-6), in a mixture with the proportion 3:1 has a CAS No 55965-84-9 with the classification as stated above.

Additional information:

No need for declaration below 0,1%

4. First-aid-steps

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.

| | |
|------------------------|--|
| Inhalation: | Remove source of exposure; take person outside at fresh air |
| Skin contact: | Remove source of exposure; wash affected area with water |
| Eye contact: | Remove source of exposure; wash with copious amounts of water |
| Ingestion: | Drink copious amounts of water |
| General advice: | If irritation or signs of toxicity occur, seek medical attention |

5. Fire and Explosion Hazard Data

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|---|--|
| Extinguishing media: | Water spray, Foam, CO ₂ , Dry Chemical |
| Special hazards and safety measures in case of fire: | Special protection in case of fire-fighting is generally recommended |

6. Accidental Release

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|--|--|
| Personal precautions: | Wear protective clothes, remove unprotected persons |
| Environmental precautions: | not necessary |
| Procedures for cleaning/collecting: | Spilled liquid should be wiped away with absorbent material and be submitted to disposal |
| Additional advice: | No hazardous compounds are released |

7. Handling and storage

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|--|--|
| Protective measure for safe handling: | No special measures required, observe instructions for use |
| Conditions for safe storage: | see package insert |

8. Exposure control and personal protection

| | |
|---|---|
| Addition information about design of technical facilities: | not necessary |
| General protective and hygiene measures: | Keep away from food and beverages Wash hands |
| Protection of hands/eyes: | Protective lab glasses, gloves |
| Personal protection: | Laboratory clothes |
| Respiratory protection: | not necessary |

9. Physical and chemical properties

| | Components | |
|--------------------------------------|----------------|-------------------------------------|
| | MQBHIT | MQSHIT |
| Form | liquid | solid |
| colour | colourless | white |
| Odour | No smell | No smell |
| pH (20°C) | ~ pH 7 | Not applicable for solid components |
| Melting point/ Freezing point | Do not freeze | Plastic decomposition at ~ 300°C |
| Boiling point (°C) | ~ 100°C | Not applicable for solid components |
| Burning point (°C) | Not applicable | Not applicable |
| Evaporation rate | Not applicable | Not applicable |
| Ignition temperature | Not applicable | Not applicable |
| flammability | Not applicable | Not applicable |
| Relative vapour pressure | Not applicable | Not applicable |
| Relative vapour density | Not applicable | Not applicable |
| Solubility | soluble | Not applicable |
| Self-ignition (°C) | Not applicable | Not applicable |
| Explosive character | Not applicable | Not applicable |

10. Stability and reactivity

| | |
|---|--|
| Conditions to be avoided: | Humidity (opened test), heating up, drying up |
| Compounds to be omitted: | No special hazards known |
| Hazardous products of decomposition: | Plastic device; Strip: hazardous decomposition products during burning possible |

11. Toxicological information

| | |
|--|---|
| Primary irritant effect on the eyes / skin: | Data concerning the toxicity of this product in the existing dilution are not available |
| Sensitization of respiratory system / skin: | No irritant effect known |
| Additional information: | The product should be used taking the usual precautions for handling chemicals |

12. Ecological information

No data required. Test can be thrown away in regular household garbage.
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

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|--------------------------------------|---|
| <u>Procedure of disposal:</u> | Follow the standard procedures for proper disposal of specimens |
|--------------------------------------|---|

14. Transport information

| | |
|---|--------------------|
| UN-transport identification ADR/RID: | not subject |
| Hazard category for transportation: | not applicable |
| Environmental risks: | none |
| Special information for the user: | see chapter 6 to 8 |

15. Regulations

| | |
|---|-------------------|
| Labeling according to EC Directives: | no classification |
| Risk (H) and safety (P) phrases: | not necessary |

National Regulations

| | |
|------------------------------------|-------------------------------|
| Water hazard class: | WGK 0: not hazardous to water |
| Chemical Safety Assessment: | not necessary |

16. Other information

Changes compared to revised version: ---

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.

Material Safety Data Sheet issued by:

S. Mauracher
Safety Officer Medical Device

Date of issue of the Material Safety Data Sheet: 01. March 2016

