

Safety Data Sheet

according to Regulation (EC) No 1907/2006

HISTO SPOT® AB Reagent Kit

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

This Safety Data Sheet is for the following products:

HISTO SPOT® AB Reagent Kit : Order-no. 728198

Product Components:

SAMBUF (60 ml), CONJBUF (40 ml), CONJ I AB (40 µl), SUBS I AB (40 ml), Wash I 1 (2x 120 ml)

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

Use of the substance/mixture

For in vitro diagnostic use.

1.3. Details of the supplier of the safety data sheet

| | | |
|-----------------|--|--------------------------------|
| Company name: | BAG Diagnostics GmbH | |
| Street: | Amtsgerichtsstr. 1-5 | |
| Place: | D-35423 Lich | |
| Telephone: | +49 (0)6404 925-100 | Telefax: +49 (0)6404 925-460 |
| e-mail: | info@bag-diagnostics.com | |
| Contact person: | Dr. Evelyn Sachsenberg | Telephone: +49 (0)6404 925-217 |
| e-mail: | e.sachsenberg@bag-diagnostics.com | |
| Internet: | www.bag-diagnostics.com | |

1.4. Emergency telephone number:

Extern: +49 (0)6131-19-240 Medizinische Klinik der Universität Mainz
Intern: +49 (0)171-2157379

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1907/2006 and (EC) No. 1272/2008 identifies that these product components are not dangerous.

Proclin (mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)): 0.05%: not hazardous at this concentration.

EDTA (Ethylenediamine Tetraacetic Acid): 0.32% not hazardous at this concentration.

TMB Membrane Single Component: Mixture: Aqueous buffered solution containing 3,3',5,5' Tetramethylbenzidine, Sodium Perborate and MethylisoThiazolone (preservative = mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-4-isothiazolin-3-one).

HAZARDOUS SUBSTANCES: 5-Chloro-2-methyl-4-isothiazolin-3-one (CAS / EINECS 26172-55-4)

2-Methyl-4-isothiazolin-3-one (CAS / EINECS 2682-20-4) Concentration in mixture: < 20 ppm (total); non hazardous at concentration used.

2.3. Other hazards

No dangers to be mentioned. Please observe the safety information of the safety data sheet.

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

SAMBUF

ProClin 300 (CAS Number 55965-84-9): Concentration 0.05%

EDTA (CAS Number 60-00-4): Concentration 0.32%

Contains material from bovine and avian origin

CONJBUF

ProClin 300 (CAS Number 55965-84-9): Concentration 0.05%

Contains material from bovine and avian origin

CONJ I AB

EDTA (CAS Number 60-00-4): Concentration 0.32%

Contains material from bovine and avian origin

SUB I AB

TMB Membrane Single Component: Mixture: Aqueous buffered solution containing 3,3',5,5' Tetramethylbenzidine, Sodium Perborate and MethylIsoThiazolone (preservative = mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-4-isothiazolin-3-one).

WASHBUF

ProClin 300 (CAS Number 55965-84-9): Concentration 0.5%

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Aerosols: Provide with fresh air. Seek medical advice.

After contact with skin

On contact with the skin, wash off immediately with soap and water. Seek medical advice.

After contact with eyes

On contact with the eyes, rinse the eyes with water with the eyelids open for a sufficient length of time, then seek medical (ophthalmological) advice immediately.

After ingestion

Rinse out mouth and then drink plenty of water. Seek medical advice.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water. Foam. Dry powder. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

With heating up or in case of open fire poisonous gases are possible.

5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective clothing.

Additional information

Do not inhale combustible gases.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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Ensure adequate ventilation. Avoid contact with skin and eyes.

6.2. Environmental precautions

Do not allow to enter drains/surface waters/groundwater. Treat recovered material as prescribed in "Disposal considerations".

6.3. Methods and material for containment and cleaning up

Take up buried product. Usual absorbing materials are sufficient.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Observe the general safety regulations for laboratories. Wear suitable protective clothing, gloves and eye/ face protection. Avoid skin and eye contact. Provide sufficient ventilation.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Storage at 4°C

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Protective and hygiene measures

While working wear laboratory coats, eye protection and gloves. Always wash hands with water and soap after test procedure. The glove material must be impervious against the product. Due to missing tests, no recommendations regarding the selection of the glove material can be given.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|-----------------|------------------------------------|
| Physical state: | liquid |
| Colour: | Clear and slightly yellow to amber |
| Odour: | Slight odor of poultry |
| pH-Value: | not applicable |

Changes in the physical state

| | |
|--|--------------------|
| Melting point: | not available |
| Initial boiling point and boiling range: | not available |
| Sublimation point: | not available |
| Softening point: | not available |
| Flash point: | not available |
| Water solubility: | completely mixable |

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available

10.2. Chemical stability

No information available

10.3. Possibility of hazardous reactions

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No information available

10.4. Conditions to avoid

Strong heating above room temperature

10.5. Incompatible materials

No information available

10.6. Hazardous decomposition products

No information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

No harmful effects reported.

Additional information on tests

Handled properly, no toxic effects are expected.

The product has to be handled with the caution usual for chemicals.

SECTION 12: Ecological information

12.1. Toxicity

slightly water contaminating

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

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

There are no standardized regulations in EEC for disposal and/ or residual substances. Chemicals, which result as residual substances, are usually hazardous waste. Their removal is regulated by appropriate laws and/ or regulations of the EEC-Member countries as well as for the Federal Republic of Germany. Please contact the competent authority (e.g. waste disposal enterprises).

SECTION 14: Transport information

Other applicable information

The product is not subordinated to the transportation regulation.

SECTION 15: Regulatory information

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

National regulatory information

Water contaminating class (D): 1 - slightly water contaminating

Additional information

The product is not a hazardous preparation according to Directive 67/548/EEC, 1999/45/EC and Regulation 1272/2008/EC (GHS)

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SECTION 16: Other information

Further Information

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

Disclaimer

For in-vitro-diagnostic use only.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)