Safety data sheet in accordance with 1907/2006/EC

Trade name: Hemoglobin microcuvette for Hemo Control Photometer

Current version: 2.0.0, issued: 06.06.2012 Replaced version: 1.1.0, issued: 27.04.2010 Region: GB

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

1.1 Product identifier

Trade name

Hemoglobin microcuvette for Hemo_Control Photometer

Order No. 3000-3011-050

Order No. 3000-3012-xxxx

Order No. 3000-3013-0278

Order No. 3000-3021-0284

Order No. 3002-3422-0378

Order No. 3003-3514-xxxx

Order No. 3011-3011-0276

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

Relevant identified uses of the substance or mixture

In-vitro-diagnosticum

Microcuvettes for determining the hemoglobin level in venous and capillary blood

Only for use with the EKF Hemo_Control, Hemo_Control Manager device or with compatible instruments

1.3 Details of the supplier of the safety data sheet

Address

EKF diagnostic GmbH Ebendorfer Chaussee 3 D-39179 Barleben

Telephone no. +49 (0)3 92 03 / 7 85 - 0 Fax no. +49 (0)3 92 03 / 7 85 - 16

Information provided by / telephone

EKF diagnostic GmbH

Telephone: +49 (0)39203 / 785 - 0 (7 am - 4 pm on workdays)

Advice on Safety Data Sheet

support@ekf-diagnostic.de

1.4 Emergency telephone number

+49 (0) 551 / 19240 Poison Information Centre North(Giftinformationszentrale Nord)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification information

This product is in the sense of article 3 of the Regulation (EC) 1907/2006 (REACH) an article and not subject to the labelling obligations according to:

- Art. 1, Regulation (EC) 1272/2008 (CLP);
- Article 12.(2), Directive 1999/45 (DPD).

To provide a safety data sheet is not mandatory for articles and is done on a voluntary basis.

2.2 Label elements

Not relevant

2.3 Other hazards

Please observe the information given in this safety data sheet.



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SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable. The product is not a substance.

3.2 Mixtures

Chemical characterization

Microcuvettes for determining the hemoglobin lecvel in venous and capillary blood

Additional ingredients

| No | Substance name | | Addit | ional info | rmati | on | |
|----|--------------------|---------------------------------------|-------|------------|-------|--------|--------|
| | CAS / EC / Index / | Classification 67/548/EEC | Conc | entration | | | %-b.w. |
| | REACH no | | | | | | |
| | polystyrene | | | | | | |
| | 9003-53-6 | - | | | < | 100,00 | %-b.w. |
| | - | | | | | | |
| | - | | | | | | |
| | - | | | | | | |
| | sodium 3-alpha,12- | alpha-dihydroxy-5-beta-cholan-24-oate | | | | | |
| | 302-95-4 | - | < | 0,05 | | | %-b.w. |
| | 206-132-7 | | | | | | |
| | - | | | | | | |
| | - | | | | | | |

Hazardous ingredients

This product does not contain substances to be mentioned according to EU Regulation No 1907/2006 (REACH), annex II.

3.3 Other information

The reagents are in an opening on the surface of the cuvette.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

In case of persisting adverse effects, consult a physician. Change contaminated, saturated clothing.

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

Seek medical advice immediately. Rinse mouth thoroughly with water. 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

Foam; Carbon dioxide; extinguishing powder; Water spray jet

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Unsuitable extinguishing media

No data available.

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. Ensure adequate ventilation.

For emergency responders

No data available. 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

Take up mechanically. When picked up, treat material as prescribed under 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

No special measures necessary if stored and handled as prescribed.

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.

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 and dry in a cool, well-ventilated place.

Requirements for storage rooms and vessels

Keep the product in the original packing.

Advice on storage assembly

None known

7.3 Specific end use(s)

No data available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

No parameters available for monitoring.

8.2 Exposure controls

Appropriate engineering controls

No data available.

Personal protective equipment

Respiratory protection

No special measures required.

Eye / face protection

Safety glasses recommended

Hand protection

Sufficient protection is given wearing suitable protective gloves checked according to i.e. EN 374, in the event of risk of skin contact with the product. Before use, the protective gloves should be tested in any case for its specific workstation 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

Check suitability of protective clothing for the specific workplace conditions. Chemical resistance of the protective equipment should be discussed with the manufacturer of the protective equipment.

Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| Form/Colour | | | |
|-------------------|---|--|--|
| cuvette | | | |
| yellow | | | |
| Odour | | | |
| odourless | | | |
| Odour threshold | | | |
| No data available | | | |
| pH value | | | |
| Value | 6,8 | | |
| Remarks | Remarks 5 cuvettes in 20 ml deionized water | | |



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| Boiling point / boiling range | |
|--|---|
| No data available | |
| Melting point / melting range | |
| No data available | |
| Decomposition point / decomposition range | |
| No data available | _ |
| Flash point | |
| No data available | |
| Auto-ignition temperature No data available | |
| | |
| Oxidising properties No data available | |
| | |
| Explosive properties No data available | |
| Flammability (solid, gas) | |
| No data available | |
| Lower flammability or explosive limits | |
| No data available | |
| Upper flammability or explosive limits | |
| No data available | |
| Vapour pressure | |
| No data available | |
| Vapour density | |
| No data available | |
| Evaporation rate | |
| No data available | |
| Relative density | |
| No data available | |
| Density No data available | |
| | |
| Solubility in water No data available | |
| Solubility(ies) | |
| No data available | |
| Partition coefficient: n-octanol/water | |
| No data available | |
| Viscosity | |
| No data available | |
| | |

9.2 Other information

| Other information | |
|--------------------|--|
| No data available. | |

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SECTION 10: Stability and reactivity

10.1 Reactivity

No data available.

10.2 Chemical stability

No data available.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

None known

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

| 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

Delayed and immediate effects as well as chronic effects from short and long-term exposure

When handled appropriately adverse health effects are not to be expected.



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SECTION 12: Ecological information

12.1 Toxicity

| Fish toxicity | |
|-------------------|--|
| No data available | |
| | |

Daphnia toxicity No data available

| Algae toxicity | |
|-------------------|--|
| 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

No data available.

12.6 Other adverse effects

No data available.

12.7 Other information

Other information

Ecological data are not 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

Residuals 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.



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SECTION 14: Transport information

14.1 Transport ADR/RID/ADN

The product is not subject to ADR/RID/ADN regulations.

14.2 Transport IMDG

The product is not subject to IMDG regulations.

14.3 Transport ICAO-TI / IATA

The product is not subject to ICAO-TI / IATA regulations.

14.4 Other information

No data available.

14.6 Special precautions for user

No data available.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture No data available.

15.2 Chemical safety assessment

No data available.

SECTION 16: Other information

Sources of key data used to compile the data sheet:

EC Directive 67/548/EC resp. 99/45/EC as amended in each case.

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

EC Directives 2000/39/EC, 2006/15/EC, 2009/161/EC

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 chapter.

Department issuing safety data sheet

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This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.