

Trade name: DiaSpect Control HBT

Current version : 1.0.1, issued: 20.06.2018

Replaced version: 1.0.0, issued: 14.06.2018

Region: GB

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

1.1 Product identifier

Trade name

DiaSpect Control HBT

DiaSpect Control Pack HBT1 (90B.0011)

DiaSpect Control Pack HBT2 (90B.0012)

DiaSpect Control Pack HBT3 (90B.0013)

DiaSpect Control Pack HBT4 (90B.0014)

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

Relevant identified uses of the substance or mixture

For verification of the precision and accuracy of DiaSpect hemoglobinometers and DiaSpect Hemoglobin Cuvettes.
For in vitro diagnostic use only.

Uses advised against

No data available.

1.3 Details of the supplier of the safety data sheet

Address

EKF-diagnostic GmbH
Ebendorfer Chaussee 3
39179 Barleben
Germany

Telephone no. +49(0)39203511-0
Fax no. +49(0)39203511-171

Information provided by / telephone

Telephone number +49(0)39203511-0

Advice on Safety Data Sheet

support@ekf-diagnostic.de

Identification of the manufacturer / supplier

Address

Diaspect Medical GmbH
Ebendorfer Chaussee 3
39179 Barleben
Germany

1.4 Emergency telephone number

For medical advice (in German and English):
+49 (0)551 192 40 (Giftinformationszentrum Nord)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification information

This product is a medical device in accordance with the European Medical Device Directive 98/79/EEC. Therefore, according to article 1, it is not subject to the provisions of Regulation (EC) No. 1272/2008.

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).

To provide a safety data sheet is not mandatory for articles according to art. 31 of the Regulation (EC) 1907/2006 (REACH) and is done on a voluntary basis.

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2.2 Label elements

Not relevant

2.3 Other hazards

No data available.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable. The product is not a substance.

3.2 Mixtures

Hazardous ingredients

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

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.

After inhalation

Ensure supply of fresh air.

After skin contact

When in contact with the skin, clean with soap and water.

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 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

No data available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Foam; Carbon dioxide; Extinguishing powder; Water spray jet

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.

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For emergency responders

Personal protective equipment (PPE) - see Section 8.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Contain and collect spillage with non-combustible absorbent materials, e.g. sand, earth, vermiculite, diatomaceous earth and place in container for disposal according to local regulations (see section 13).

6.4 Reference to other sections

Information regarding safe handling, see chapter 7. Information regarding personal protective measures, see chapter 8. Information regarding waste disposal, see chapter 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.

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. Keep the product in the original packing.

Advice on storage assembly

Substances to be avoided, pls. See chapter 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 aerosol and mist formation, take appropriate measures for breathing protection in the event 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.

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Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form/Colour
liquid, clear
red

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Odour
No data available
Odour threshold
No data available
pH value
No data available
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

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No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

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

None known

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

No data available.

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

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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
Toxicity to algae (acute)
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

No data available.

12.6 Other adverse effects

No data available.

12.7 Other information

Other information
Do not discharge product unmonitored into the environment.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Dispose of according to all applicable regulations upon consultation of the local competent authorities and the disposer in a suitable and authorised 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

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.

14.5 Environmental hazards

Information on environmental hazards, if relevant, please see 14.1 - 14.3.

14.6 Special precautions for user

No data available.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not relevant

SECTION 15: Regulatory information

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

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 article 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, PREPARATIONS AND ARTICLES

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances

This product is not subject to Part 1 or 2 of Annex I.

Other regulations

Adhere to the national sanitary and occupational safety regulations when using this product.

15.2 Chemical safety assessment

No data available.

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.

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

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.

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Department issuing 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.

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