

Trade name: BCG-medac / Vejicur® (Bacillus Calmette-Guérin)

Version: 3.0.2 / GB

Status: 23.09.2010
Date of printing: 23.09.2010**1.) Identification of the substance/preparation and of the company/undertaking****Identification of the substance or preparation****Trade name****BCG-medac / Vejicur® (Bacillus Calmette-Guérin)****Use of the substance/preparation**

pharmaceutical products

Company/undertaking identification**Address**medac Gesellschaft für klinische Spezialpräparate mbH
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20354 Hamburg

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Information provided by / telephone

Wedel site: Tel: +49 (4103)-8006-0; Fax: +49 (4103)-8006-100

Emergency telephone

For medical advice (in German and English):

+49 (0)551 192 40 (Giftinformationszentrum Nord)

Advice on Safety Data Sheet

sdb_info@umco.de

2.) Hazards identification**Particular information pertaining specific risk for human / environment**

Although this product is not subject to reporting requirements for hazardous products, we recommend compliance with the safety recommendations.

3.) Composition / information on ingredients**Chemical characterization**

aqueous solution of at least 2X10E8 and not more than 3X10E9 vital units of BCG (Bacillus Calmetta-Guérin).

4.) First aid measures**General information**

In case of persisting adverse effects, consult a physician.

After inhalation

In the event of symptoms take medical treatment. Ensure supply of fresh air.

After skin contact

Spillage on the skin should be treated with an appropriate disinfectant.

After eye contact

In case of contact with eyes rinse thoroughly with plenty of water. If symptoms persist, seek medical advice.

After ingestion

Rinse out mouth and give plenty of water to drink.

5.) Fire-fighting measures**Suitable extinguishing media**

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas.

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases

No risks known.

Special protective equipment for fire-fighters

Fire-fighting operations, rescue and clearing work under effect of combustion and smoulder gases just may be done with breathing apparatus.

Other information

Run-off water from fire fighting must not be discharged into drains or enter surface water.

6.) Accidental release measures**Personal precautions**

Use personal protective clothing.

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Irritant/corrosive effects

Irritant effect on skin

Remarks No data available.

Irritant effect on eyes

Remarks No data available.

Sensitisation

Remarks No data available.

Effects after repeated or prolonged exposition (subacute, subchronic, chronic)

Mutagenicity

Remarks No data available.

Reproduction toxicity

Remarks No data available.

Carcinogenicity

Remarks No data available.

12.) Ecological information

Ecotoxicity

Fish toxicity

Remarks No data available.

Daphnia toxicity

Remarks No data available.

Algae toxicity

Remarks No data available.

Bacteria toxicity

Remarks No data available.

Other information

Do not discharge product unmonitored into the environment.

13.) Disposal considerations

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

Uncontaminated packaging may be taken for recycling. Packaging that cannot be cleaned should be disposed off as product waste.

14.) Transport information

Other information (chapter 14.)

No hazardous material as defined by the transport regulations.

15.) Regulatory information

Labelling in accordance with EC directives

The product is not subject to the chemicals act. However it has been classified according to the rules of the chemicals act, so that the precautionary measures comply with the procedures generally foreseen for chemicals handling and to make them comparable.

16.) Other information

Further information

Please read packing specification of the drug for additional drug related information.

The information is based on our current knowledge however it does not represent a guarantee of product properties nor does it create any legal obligation.

The data of this safety data sheet reflect the actual state of knowledge. The safety data sheet describes the product in view of its handling and safety relevant requirements of the pharmaceutical ingredient as bulk ware (chemical).

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) as amended in each case.

EC Directives 2000/39/EC, 2006/15/EC as amended in each case.

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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Ready-made medical preparations are not ruled by the chemical's act, so that the submission of a safety data sheet is not obligatory. Medac, however, opts for this form because the safety data sheet constitutes a reliable source of information regarding the handling of hazardous substances and preparations, and because many occupational safety measures are basing on the safety data sheet structure.