

Material Safety Data Sheet

According to 91/155 EC

Printing date 12.12.2003

Reviewed on 12.12.2003

1 Identification of the substance/preparation and of the company/undertaking

- **Product details**
- **Trade name:** Clostridium difficile Positiv - Kontrolle
- **Article number:** C 0801-07
- **Application of the substance / the preparation:** In vitro Diagnostica
- **Manufacturer/Supplier:**
R-Biopharm AG
Landwehrstr. 54
D-64293 Darmstadt
- Tel.: 0049 / 6151 / 8102-0
- **Further information obtainable from:** FE
- **Information in case of emergency:** FE 0049-6151-8102-0

*

2 Composition/information on ingredients

- **Chemical characterization**
- **Description:**
Mixture of substances with nonhazardous additions.
Partially denaturated toxin < 0,1%
- **Dangerous components:** Void
- **Additional information:** For the wording of the listed risk phrases refer to section 16.

3 Hazards identification

- **Hazard description:** Not applicable.
- **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

4 First-aid measures

- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.

5 Fire-fighting measures

- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Person-related safety precautions:** Wear protective clothing.
- **Measures for environmental protection:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.

(Contd. on page 2)

GB

Material Safety Data Sheet

According to 91/155 EC

Printing date 12.12.2003

Reviewed on 12.12.2003

Trade name: Clostridium difficile Positiv - Kontrolle

(Contd. of page 1)

- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Additional information:** No dangerous substances are released.

7 Handling and storage

- **Handling:**
- **Information for safe handling:** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Goggles recommended during refilling

9 Physical and chemical properties

· General Information

Form:	Fluid
Colour:	Colourless
Odour:	Characteristic

· Change in condition

Melting point/Melting range: Undetermined.

(Contd. on page 3)

GB

Material Safety Data Sheet

According to 91/155 EC

Printing date 12.12.2003

Reviewed on 12.12.2003

Trade name: Clostridium difficile Positiv - Kontrolle

(Contd. of page 2)

Boiling point/Boiling range: 100°C	
· Flash point:	Not applicable.
· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Vapour pressure at 20°C:	23.0 hPa
· Density:	Not determined.
· Solubility in / Miscibility with water:	Fully miscible.
· Solvent content:	
Organic solvents:	0.0 %
Water:	50.0 %

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Dangerous reactions** No dangerous reactions known.
- **Dangerous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13 Disposal considerations

- **Product:**
- **Recommendation** Autoclave or dispose as hazardous waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

(Contd. on page 4)

GB

Material Safety Data Sheet

According to 91/155 EC

Printing date 12.12.2003

Reviewed on 12.12.2003

Trade name: Clostridium difficile Positiv - Kontrolle

(Contd. of page 3)

· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· **Land transport ADR/RID (cross-border)**

· **ADR/RID class:** -

· **Maritime transport IMDG:**

· **IMDG Class:** -

· **Marine pollutant:** No

· **Air transport ICAO-TI and IATA-DGR:**

· **ICAO/IATA Class:** -

· **Transport/Additional information:** Not dangerous according to the above specifications.

15 Regulatory information

· **Labelling according to EU guidelines:**

Observe the general safety regulations when handling chemicals.

The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).

· **National regulations:**

· **Waterhazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing MSDS:** QS

· **Contact:** QS 0049-6151-8102-0

· *** Data compared to the previous version altered.**

GB