

Material Safety Data Sheet

According to 91/155 EC

Printing date 12.12.2003

Reviewed on 12.12.2003

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

· **Product details**

· **Trade name:** Clostridium difficile Biotin Conjugate

· **Article number:** C 0801-03

· **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.

· **Dangerous components:**

	FCS		25-50%
CAS: 26628-22-8	sodium azide	 T+,  N; R 28-32-50/53	£0.1%
EINECS: 247-852-1			

· **Additional information:** For the wording of the listed risk phrases refer to section 16.

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3 Hazards identification

· **Hazard description:**



Xn Harmful

· **Information concerning particular hazards for human and environment:**

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

R 22 Harmful if swallowed.

· **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:**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· **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:** Call for a doctor immediately.

5 Fire-fighting measures

· **Suitable extinguishing agents:**

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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· **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.
- **Measures for cleaning/collecting:**
 - Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
 - Dispose contaminated material as waste according to item 13.

7 Handling and storage

- **Handling:**
 - **Information for safe handling:** Open and handle receptacle with care.
 - **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:**

26628-22-8 sodium azide

OES	Short-term value: 0.3 mg/m ³ Long-term value: 0.1 mg/m ³ as NaN ₃ , New, IOELV, Sk
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- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
 - **General protective and hygienic measures:**
 - Keep away from foodstuffs, beverages and feed.
 - Wash hands before breaks and at the end of work.
 - **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.

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· **Eye protection:** Goggles recommended during refilling

9 Physical and chemical properties

· General Information

Form:	Fluid
Colour:	Blue
Odour:	Characteristic

· Change in condition

Melting point/Melting range: Undetermined.
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:	68.8 %

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:

· **LD/LC50 values relevant for classification:**

26628-22-8 sodium azide

Oral	LD50	27 mg/kg (rat)
Dermal	LD50	20 mg/kg (rabbit)

· **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 shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

Harmful

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* 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.

· **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:**

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.

· **Code letter and hazard designation of product:**

Xn Harmful

· **Hazard-determining components of labelling:**

sodium azide

· **Risk phrases:**

22 Harmful if swallowed.

· **Safety phrases:**

36 Wear suitable protective clothing.

45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

60 This material and its container must be disposed of as hazardous waste.

· **National regulations:**

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

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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.

· **Relevant R-phrases**

28 Very toxic if swallowed.

32 Contact with acids liberates very toxic gas.

50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· **Department issuing MSDS:** QS

· **Contact:** QS 0049-6151-8102-0

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

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