

Safety Data Sheet: *Helicobacter direct* PCR

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830



Date of issue: 26.06.2026

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

1.1 Product identifier

Product name	Helicobacter <i>direct</i> PCR
Product code	FBC116-Ax FBC116-Bx
Content	Solution A Internal Control Positive Control

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

No additional information available.

Restrictions on Professional Use of Medical Devices
use:

1.3 Details of the supplier of the safety data sheet

Manufacturer	FRIZ Biochem GmbH Floriansbogen 2-4 D-82061 Neuried Tel.: +49 (0) 89 724409 0
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1.4 Emergency telephone number

Manufacturer	Tel.: +49 (0) 89 724409 0
Emergency number Munich Germany	Tel.: +49 (0) 89 19240

1 Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] Not classified

2.2 Label elements

According to EC directives or the corresponding national regulations there is no labelling obligation for this product.

2.3 Other hazards

None

2 Composition/Information on ingredients

3.1. Substances:

Not applicable

3.2. Mixtures

Not applicable

3 First aid measures

4.1 Description of first aid measures

After inhalation: Fresh air supply, consult a doctor in case of physical complaints.

After eye contact: Rinse opened eyes with plenty of water. Consult an ophthalmologist.

After skin contact: Rinse with plenty of water. Contact a doctor if skin irritation persists.

After swallowing: Rinse mouth out and drink water. Consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed

No additional information available

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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4 Fire-fighting procedures

5.1 Extinguishing agent

Suitable extinguishing agent	Adapt fire-fighting measures to the immediate surroundings.
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5.2 Special hazards arising from the substance or mixture

None known

5.3 Advice for firefighters

Protective clothing: Do not attempt to take action without suitable protective equipment.

5 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal protective equipment	Do not attempt to take action without suitable protective equipment
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6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Take up liquid spill into absorbent material. Make sure the room is well-ventilated and then clean.

Reference to other sections

For further information refer to section 7/8/13.

7 Handling and storage

7.1 Precautions for safe handling

Handling	No special handling necessary if stored and handled according to instructions. Avoid contact with spilled reagents.
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Protection against fire and explosion	No special measures necessary.
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7.2 Conditions for safe storage, including any incompatibilities

Storage	Store product according to labelling. Keep away from incompatible materials. Keep under lock and key.
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7.3 Specific end use(s)

No additional information available.

8 Exposure limitation and controls/personal protection

8.1 Control parameters

No additional information available

8.2 Exposure controls

General protective and hygiene measures

The usual precautions when handling chemicals must be observed.

- Do not smoke, eat, or drink when working.
- Keep away from food and drink.
- Wash hands before breaks and after work.
- Avoid contact with eyes and skin.
- Immediately remove soiled or soaked clothing.

Personal protective clothing

Respiratory protection	No special measures necessary.
Eye protection	Safety goggles (DIN EN 166) recommended

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Body protection	Standard laboratory work clothing
Hand protection	Protective gloves (DIN EN 455). The protective gloves should, in all cases, be checked for their workplace-specific suitability (e.g. mechanical resistance, product compatibility, anti-static properties). Follow the instructions and information from the protective glove manufacturer concerning the use, storage, maintenance, and replacement of gloves. If damaged or showing initial wear marks, the protective gloves should be replaced immediately. Arrange work processes in such a way that the gloves need not be worn continuously.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

	Solution A	Internal Control	Positive Control
Physical state	Liquid	Liquid	Liquid
Colour	Clear	Clear	Clear
smell	Odourless	Odourless	Odourless
Melting point	Not determined	Not determined	Not determined
Boiling point	Not determined	Not determined	Not determined
Density:	Not determined	Not determined	Not determined
Risk of explosion	Non explosive	Non explosive	Non explosive
Flash point:	Not applicable	Not applicable	Not applicable
Density:	No data available	No data available	No data available
Solubility	No data available	No data available	No data available

9.2 Other information

None

10 Stability and reactivity

10.1 Reactivity

No further information available.

10.2 Chemical stability

Stable under intended use conditions.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

No further information available.

10.5 Incompatible materials

No further information available.

10.6 Hazardous decomposition products

No further information available.

11 Toxicological information

11.1 Information on toxicological effects

No information available.

12 Environmental information

The product does not contain substances which are hazardous for the environment.

13 Disposal considerations

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13.1 Waste treatment methods

Product: The allocation of a waste code number must be made in accordance with the European Waste Catalogue (AVV-Waste List Ordinance) in consultation with the regional disposer. Should not be released into the environment.

Packaging: Disposal in accordance with official regulations

14 Transport information

Not subject to transport regulations according to ADR, RID, IATA and IMDG.

15 Regulatory information

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

- National regulations: Not applicable.
- Information about limitation of use: Note the limitations of use for young persons in accordance with Section 22 JArbSchG.
- Hazardous Incidents Ordinance: Not applicable.
- Classification according to VbF: Not applicable.
- Water hazard class: Not hazardous to water.
- Chemical safety assessment: No chemical safety assessment has been carried out.

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

16 Other information

The information is based upon our present knowledge. It is intended to describe our products in terms of safety requirements but does not represent any undertaking as regards product quality, nor does it constitute any contractual legal obligation.

Section issuing the data sheet: Department of Occupational Safety

Contact: Olga Bazhanova

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative
