

Safety Data Sheet

As per 1907/2006/EG, Article 31

Positive Control

Modaplex *Clostridium difficile* Analysis Kit

Version: 1.0

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1. Name of the substance / preparation and name of the company

Product identifier

Product name: Positive Control

Relevant identified uses

Laboratory chemicals

Relevant uses advised against

No further relevant information available.

Information about the manufacturer / supplier

Company name: Biotype Innovation GmbH
Address: Moritzburger Weg 67
D-01109 Dresden
Deutschland
E-mail: info@biotype-innovation.com

Emergency contact number

+49 351 8838 4500

2. Hazards identification

Classification of the substance / preparation

Classification according to Regulation EG 1272/2008 (CLP)

This substance / preparation does not meet the criteria for being classified according to EG 1272/2008 and is therefore categorized as not dangerous.

Additional information

Not applicable.

Label elements

Labelling according to Regulation EG 1272/2008 (CLP)

This substance / preparation does not meet the criteria for being classified according to EG 1272/2008 and therefore does not need to be labelled.

Hazard pictogram

Not applicable.

Signal word

Not dangerous.

Hazard statements

Not applicable.

Precautionary statements

Not applicable.

Other hazards

This substance / preparation does not meet the criteria for PBT or vPvB substances.

3. Composition / Information on ingredients

Chemical characterization

Liquid

Description

Mixture of plasmid and a diluent buffer, which contains ProClin in 0.0006% final concentration.

Dangerous ingredients

This product does not contain any substances which at the given concentration pose a health hazard.

4. First-aid measures

Description of first aid measures

Following skin contact

Rinse with plenty of water. Call a doctor/physician if you feel unwell.

Following eye contact

Rinse cautiously with water for min. 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Consult a doctor when complaints persist.

Following ingestion

Never give anything by mouth to an unconscious person. Consult a doctor when complaints persist. Do not induce vomiting without medical advice.

Following inhalation

Bring affected person into the fresh air. Consult a doctor when complaints persist. If affected person is not breathing, provide artificial respiration.

Advice for the physician

Most important symptoms and effects, both acute and delayed

Not applicable.

Indication of any immediate medical attention and special treatment needed

Not applicable.

5. Fire fighting measures

Extinguishing media

Suitable extinguishing media

Water spray, carbon dioxide (CO₂), alcohol-resistant foam or dry chemicals

Unsuitable extinguishing media

No information available.

Special hazards arising from the substance or preparation

No information available.

Advice for fire-fighters

Self-contained breathing apparatus and a chemical protection suit must be worn.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Wear personal protective equipment.

Environmental precautions

Take actions to prevent further leaks and spillage if it is safe to do so.

Methods and material for containment and cleaning up

Absorb with inert material.

Reference to other sections

For more information, please check section 8.

7. Handling and storage

Precautions for a safe handling

Use required protective equipment.

Precautions in case of fire and explosion

No specific measures needed.

Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptacles

Store at a dry, cold and well-ventilated place.

Further information on storage conditions

No information available.

Specific end use(s)

No relevant information available.

8. Exposure controls and personal protection

Control parameters

Components with limit values that require monitoring at the workplace

This product does not contain any components with limit values that require monitoring at the workplace.

Exposure limit

Does not contain any substances that have to be reported under current legislation.

Exposure controls

Personal protective equipment

General protective and hygienic measures

Keep away from food, drinks and animal food. Wash hands before having a break and when finished work. Avoid contact with eyes and skin.

Respiratory protection

In case of inadequate ventilation, wear respiratory protective devices and components that are tested and approved by the respective government standards.

Hand protection



Wear protective gloves.

The glove material has to be impermeable and resistant to the product / the substance / the preparation. The choice of a suitable glove is not just a question of the material: other quality factors that differ from manufacturer to manufacturer must also be considered.

Eye protection



Wear tight fitting goggles with side shields.

Skin and body protection

Wear protective clothing.

Environmental exposure controls

Prevent product from entering drains.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Liquid
Colour:	No information available
Odour:	No information available
Melting point:	°C and °F not tested
pH-value:	No information available
Decomposition temperature:	°C and °F not tested
Boiling point:	°C and °F not tested
Flash point:	°C and °F not tested
Upper explosive limit:	No information available
Lower explosive limit:	No information available
Vapour pressure:	No information available
Relative density:	No information available
Relative density:	No further relevant data available
Solubility:	Soluble
Partition coefficient:	No information available
Explosive Properties:	No information available

Further information

No further data available.

10. Stability and Reactivity

Reactivity

Unknown.

Chemical stability

Under normal conditions of use and storage stable.

Possibility of hazardous reactions

No hazardous reactions reported.

Thermal decomposition / Conditions to avoid

No further relevant data available.

Incompatible materials

No further relevant data available.

Hazardous decomposition products

None if used properly.

11. Toxicological information

Information on toxicological effects

There is no data indicating acute toxicity.

Irritation

May cause eye or skin irritation on sensitive persons. Can be dangerous if inhaled. May cause damage if ingested.

Corrosion

No corrosive effects known.

Sensitisation

No effects known.

Carcinogenicity

No carcinogen effects known.

Toxicity – single exposure

No toxic effects known.

Toxicity – repeated exposure

No toxic effects known.

Mutagenicity

No mutagenic effects known.

12. Ecological information

Toxicity

No information available.

Persistence and degradability

Potentially degradable.

Bioaccumulative potential

Does not bioaccumulate.

Mobility in soils

No information available.

Results of PBT and vPvB assessment

This substance / preparation does not contain any substances that are classified as PBT or vPvB substances.

Other adverse effects

No further relevant data available.

13. Disposal considerations

Waste treatment methods

The production of waste is to be avoided / minimized to the best possible extent. Empty container or linings may contain product residues. The substance and its container must be disposed correctly according to the approved disposal operations. The disposal of this product, its solution or by-products must meet the requirements of all relevant local, regional and national / government regulations.

14. Transport information

UN number:	None.
UN proper shipping name:	Not applicable.
Transport hazard class(es):	Not applicable.
Packing group:	Not applicable.
Environmental hazards:	Not applicable.
Special precautions for use:	Not applicable.

Transport in bulk according to
Annex II of MARPOL and the IBC code: Not applicable.

15. Regulatory information

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

Substances with significant concerns

None

In Annex 1 of Regulation (EC) Nr. 689/2008 described substances

None

Restricted substances covered by Annex V of Regulation (EC) Nr. 689/2008

None

Substances described in Regulation (EC) Nr. 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Regulation 79/117/EEC

None

German water hazard class

Not classified.

Further international assessments

Chemical safety assessment

A chemical safety assessment was not performed.

16. Other information

Data are based on our latest knowledge but do not constitute a guarantee for any specific product features and do not establish a legally valid contractual relationship.

Relevant Phrases

Not applicable.

Issuer of data sheet

Safety officer for medical devices
