

# Safety Data Sheet

As per 1907/2006/EG, Article 31

## 25X Calibrators Mix

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: 25X Calibrators Mix

#### 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](mailto:info@biotype-innovation.com)

#### Emergency contact number

+49 351 8838 4500

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## **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.

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## **3. Composition / Information on ingredients**

### **Chemical characterization**

Liquid

### **Description**

Mixture of DNA 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.

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## **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.

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## **5. Fire fighting measures**

### **Extinguishing media**

#### **Suitable extinguishing media**

Water spray, carbon dioxide (CO<sub>2</sub>), 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.

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## **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.

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## **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.

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## 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.

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## 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.

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## **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.

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## **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.

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### 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.

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### 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.

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### 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.

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### 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

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