



# SAFETY DATA SHEET

EC Regulation No. 1907/2006 (REACH) modified with 2015/830/UE

Doc. N° 271085 SSE rev.0

Date of Revision:

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## 1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1 Product identifiers

Product number:

271085

Product name:

**C. difficile Rapid Latex Test Kit**

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

Identified uses

Latex slide agglutination test for the confirmatory identification of presumptive *C. difficile* colonies.

### 1.3 Details of the supplier of the safety data sheet

Company

**Mascia Brunelli S.p.A.**

Viale Monza 272, 20128 Milano, Italy.

Tel.: 0039 02 25209.1

Fax: 0039 02 2576428

E-mail: [mktg@masciabrunelli.it](mailto:mktg@masciabrunelli.it)

### 1.4 Emergency telephone number

Emergency Phone  
Milano)

0039 02 66101029 (Centro Antiveneni Niguarda Ca' Granda –

## 2 – HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008

### 2.2 Label elements

The product does not need to be labelled in accordance with EC directives or respective national laws.

### 2.3 Other hazards – none

## 3 – COMPOSITION/INFORMATION ON INGREDIENTS

### 3.2 Mixtures

Latex, Positive Control and Diluent contain sodium azide in amounts of 0.099%. At this concentration mixtures are not classified and are not to be labelled.

## 4- FIRST AID MEASURES

### 4.1 Description of first aid measures

If swallowed

If chemicals has been swallowed, wash out mouth with water. Do not swallow mouthwash. Seek medical advice.

In case of eye contact

wash out with plenty of water.

In case of skin contact

wash skin immediately with soap and water.

### 4.2 Most important symptoms and effects, both acute and delayed

no data available

### 4.3 Indication of any immediate medical attention and special treatment needed

no data available

## 5 - FIRE-FIGHTING MEASURES

### 5.1 Extinguishing media

use dry sand cement. DO NOT USE water.

### 5.2 Special hazards arising from the substance or mixture

no data available

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### 5.3 Advice for firefighters

This material will not significantly contribute to the intensity of a fire. Use extinguishing material suitable to the surrounding fire. Utilize proper personal protective equipment when responding to any fire. Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Move containers from fire area if it can be done without risk to personnel.

## 6- ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment, lab coat and gloves

### 6.2 Environmental precautions

Given the way dispensation there is no possibility of accidental spillage in sufficient quantity to be dangerous. In any case avoid release to the environment.

### 6.3 Methods and material for containment and cleaning up

Absorb with dry earth, sand or other non combustible material. Properly disinfect any spills. Test specimens require decontamination with beach solution or appropriate germicide prior to pick up.

### 6.4 Reference to other sections

For disposal see section 13.

## 7 – HANDLING AND STORAGE

### 7.1 Precautions for safe handling

For in vitro diagnostic use. Read the instructions for Use. Always follow Good Laboratory Practice when using this product. Avoid contact with eyes, skin and clothing.

### 7.2 Conditions for safe storage, including any incompatibilities

Store at 2°C / 8°C. Keep all containers tightly closed until ready to use. Under these conditions reagents will retain the activity until the expiry date shown on the label on outer carton.

### 7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

## 8- EXPOSURE CONTROLS - PERSONAL PROTECTION

### 8.1 Control parameters

Any specific protection and prevention measures should not be taken during use of the product.

#### Components with workplace control parameters

No information available

### 8.2 Exposure controls

#### Personal protective equipment

##### Eye/face protection

Use safety glasses.

##### Skin protection

Handle with gloves. Use with a lab coat.

##### Body Protection

The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

##### Respiratory protection

Respiratory protection is not required.

## 9 – PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

	Latex	Positive Control	Diluent
a) Appearance Form:	Milky white aqueous	Clear/off white suspension	Clear solution
b) Odour	no data available		
c) Odour Threshold	no data available		
d) pH	no data available		
e) Melting point/freezing point	no data available		
f) Initial boiling point and boiling range	no data available		
g) Flash point	no data available		
h) Evaporation rate	no data available		
i) Vapour pressure	no data available		
j) Vapour density	no data available		
k) Relative density	no data available		
l) Water solubility	no data available		
m) Viscosity	no data available		
n) Explosive properties	no data available		



o) Oxidizing properties no data available

**9.2 Other safety information** no data available

## 10 – STABILITY AND REACTIVITY

<b>10.1 Reactivity</b>	No known hazardous reactivity
<b>10.2 Chemical stability</b>	Stable under recommended storage conditions.
<b>10.3 Possibility of hazardous reactions</b>	no data available
<b>10.4 Conditions to avoid</b>	avoid contact with lead or copper plumbing.
<b>10.5 Incompatible materials</b>	no data available.
<b>10.6 Hazardous decomposition products</b>	no known hazardous decomposition products

## 11 – TOXICOLOGICAL INFORMATION

<b>11.1 Information on toxicological effects</b>	
<b>Acute toxicity</b>	Product does not present an acute toxicity hazard based on known or supplied information
<b>Skin corrosion/irritation</b>	Possibility of allergic sensitization should be considered.
<b>Serious eye damage/irritation</b>	No data available.
<b>Respiratory or skin sensitisation</b>	No data available.
<b>Germ cell mutagenicity</b>	No data available.
<b>Carcinogenicity</b>	No data available.
<b>Reproductive toxicity</b>	No data available.
<b>Summary of evaluation of the CMR properties</b>	No data available.
<b>STOT-single exposure</b>	No data available.
<b>STOT-repeated exposure</b>	No data available.
<b>Aspiration hazard</b>	No data available

## 12 – ECOLOGICAL INFORMATION

<b>12.1 Toxicity</b>	no data available
<b>12.2 Persistence and degradability</b>	no data available
<b>12.3 Bio accumulative potential</b>	no data available
<b>12.4 Mobility in soil</b>	no data available
<b>12.5 Results of PBT and vPvB assessment</b>	no data available
<b>12.6 Other adverse effects</b>	no data available

## 13 – DISPOSAL CONSIDERATIONS

<b>13.1 Waste treatment methods</b>	
<b>Product</b>	Waste must be disposed of in accordance with federal, state and local environmental control regulations.
<b>Contaminated packaging</b>	Do not remove labels from containers for disposal or recycling. Observe all the attention and precautions listed for the product.

## 14 – TRANSPORT INFORMATION

The product is considered non dangerous for transportation

<b>14.1 UN number</b>	ADR/RID: - IMDG: - IATA: -
<b>14.2 UN proper shipping name</b>	ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods
<b>14.3 Transport hazard class(es)</b>	ADR/RID: - IMDG: - IATA: -
<b>14.4 Packaging group</b>	ADR/RID: - IMDG: - IATA: -
<b>14.5 Environmental hazards</b>	ADR/RID: no IMDG Marine pollutant: no IATA: no
<b>14.6 Special precautions for user</b>	no data available

## 15 – REGULATORY INFORMATION

<b>15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture</b>	This product does not require special labelling, in accordance with the appropriate EC directives. These products are used for in vitro
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diagnosis, so they must meet the criteria described in Directive 98/79/CE  
no data available

## **15.2 Chemical Safety Assessment**

## **16 – OTHER INFORMATION**

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