



## Safety Data Sheet Product Cat #: HGCDIFFR, HGCDIFFC

Product Name: HG C difficile Kit

Rev. 00 Revision date: 01 Feb. 17

### 1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE

#### 1.1 Product identifiers

Product Name: HG C difficile

Product Code: HGCDIFFR, HGCDIFFC

#### 1.2 Relevant identified uses / uses advised against

Identified uses: for IVD use only

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

Company: HiberGene Diagnostics  
Block 2, Bracken Business Park,  
Sandyford, Dublin18,  
Ireland

Telephone: +353 1 9053160

Web: [www.hibergene.com](http://www.hibergene.com)

E-mail address : [mdx@hibergene.com](mailto:mdx@hibergene.com)

#### 1.4 Emergency telephone number

Emergency Phone: +353 1 9053160

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### 2. HAZARDS

#### 2.1 Classification of the substance or mixture

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

This substance is not classified as dangerous according to Directive 67/548/EEC.

#### 2.2 Label elements

None

#### 2.3 Other hazards - none

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### 3.2 Mixtures

Contains: Component 1, Reaction Strips: Contains: oligonucleotides, fluorescent dye, nucleoside triphosphates, TE buffer solution polymerase enzyme, excipients

Component 2, Positive Control: Contains: nucleic acid, buffer solution, Proclin 950

Component 3, Dilution buffer 1: Contains: nucleic acid, buffer solution, Proclin 950

Component 4, Dilution buffer 2: Contains: nucleic acid, buffer solution, Proclin 950

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### 4. FIRST AID MEASURES

#### 4.1 Description of first aid measures

##### If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

##### In case of skin contact

Rinse thoroughly with plenty of water.

##### If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Contact a physician.

##### In case of eye contact

Flush eyes with water as a precaution.

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

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

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

No data available

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### 5. FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

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

Nature of decomposition products not known.

#### 5.3 Advice for firefighters

Wear self-contained breathing apparatus for fire-fighting if necessary.

#### 5.4 Further information

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### 6. ACCIDENTAL RELEASE MEASURES

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

Avoid breathing vapour, mist or gas.

#### 6.2 Environmental precautions

No special environmental precautions required.

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

Keep in suitable, closed containers for disposal.

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### 6.4 Reference to other sections

For disposal see section 13.

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## 7. HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Per IFU

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

Store per instructions, 2-8°C.

### 7.3 Specific end uses

IVD use only

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## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

#### Components with workplace control parameters

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

#### Appropriate engineering controls

General industrial hygiene practice.

#### Personal protective equipment / Skin protection

Handle with gloves.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

- a) Appearance: freeze dried and liquid components
- b) Odour: no data available
- c) Odour Threshold: no data available
- d) pH : no data available
- e) Melting point/freezing: no data available point
- f) Initial boiling point: no data available boiling range
- g) Flash point: not applicable no data available
- h) Evaporation rate: no data available
- i) Flammability: no data available
- j) Upper/lower: no data available flammability or explosive limits

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- k) Vapour pressure: no data available
- l) Vapour density: no data available
- m) Relative density: no data available
- n) Water solubility: no data available
- o) Partition coefficient: no data available
- p) Auto-ignition: no data available temperature
- q) Decomposition: no data available temperature
- r) Viscosity: no data available
- s) Explosive properties: no data available
- t) Oxidizing properties: no data available

### 9.2 Other safety information

None

## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

Stable under normal conditions

### 10.2 Chemical stability

no data available

### 10.3 Possibility of hazardous reactions

no data available

### 10.4 Conditions to avoid

no data available

### 10.5 Incompatible materials

no data available

### 10.6 Hazardous decomposition products

Other decomposition products - no data available



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### 11. TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

##### Acute toxicity

no data available

##### Skin corrosion/irritation

no data available

##### Serious eye damage/eye irritation

no data available

##### Respiratory or skin sensitization

no data available

##### Germ cell mutagenicity

no data available

##### Carcinogenicity

no known carcinogens contained in this product at harmful levels

##### Reproductive toxicity

no data available

##### Specific target organ toxicity - single exposure

no data available

##### Specific target organ toxicity - repeated exposure

no data available

##### Aspiration hazard

no data available

##### Potential health effects

**Inhalation** May be harmful if inhaled. May cause irritation.

**Ingestion** May be harmful if swallowed.

**Skin** May be harmful if absorbed through skin. May cause skin irritation.

**Eyes** May cause eye irritation.



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### 12. ECOLOGICAL INFORMATION

**12.1 Toxicity:** no data available, contains no known concentrations

**12.2 Persistence and degradability:** no data available

**12.3 Bioaccumulative potential:** no data available

**12.4 Mobility in soil:** no data available

**12.5 Results of PBT and vPvB assessment:** no data available

**12.6 Other adverse effects:** no data available

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### 13. DISPOSAL CONSIDERATIONS

#### Waste treatment methods

**Product:** should be disposed of in accordance in with all local and state laws and regulations.

**Contaminated packaging:** dispose of as unused product.

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### 14. TRANSPORT INFORMATION

#### 14.1 UN number

ADR/RID: - N/A

IMDG: - N/A

IATA: - N/A

#### 14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

#### 14.3 Transport hazard class(es)

No Hazards

No Hazards

#### 14.4 Packaging group

#### 14.5 Environmental hazards

ADR/RID: No Hazards

IMDG: No Hazards

IATA: No Hazards

#### 14.6 Special precautions for user

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### 15. REGULATORY INFORMATION

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture** no data available

**15.2 Chemical Safety Assessment** no data available

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### 16. OTHER INFORMATION

For further information, contact HiberGene Diagnostics.

[www.hibergene.com](http://www.hibergene.com)

[mdx@hibergene.com](mailto:mdx@hibergene.com) Tel. +353 1 9053160