



Safety Data Sheet Product Cat #: HGCTNGR, HGCTNGC

Product Name: HG CT/NG Combo Kit

Rev. 00 Revision date: 24 APR 19

1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE

1.1 Product identifiers

Product Name: HG CT/NG Combo

Product Code: HGCTNGR, HGCTNGC

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

E-mail address : mdx@hibergene.com

1.4 Emergency telephone number

Emergency Phone: +353 1 9053160

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.2 Mixtures

HGCTNGR contains:

Component 1, Reaction Strips: Contains: Buffer Solution.

Component 2: Resuspension buffer: Contains: TE buffer solution, ProClin & target plasmid (inactive)

HGCTNGC (Positive Control) contains: buffer solution & target plasmid (inactive).

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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

No known 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

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

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.

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

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
- k) Vapour pressure: no data available
- l) Vapour density: no data available



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- 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

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.

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

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

16. OTHER INFORMATION

For further information, contact HiberGene Diagnostics.

www.hibergene.com

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