

SAFETY DATA SHEET



In accordance with Regulation (EC) No 1907/2006
Revision date: 09/09/2019
Version number: SDS319v01

1. Identification of the substance or preparation and the company/ undertaking

1.1 Product Identifier

Product Name: MAST ISOPLEX®CRE-ART

Product Code: DNA/LYO5

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

Recommended uses: *In vitro* diagnostic product; Laboratory chemical

Uses advised against: No information available

1.3 Details of supplier of the product and safety data sheet

Manufacturer/supplier: Mast Group Ltd., Mast House,
Derby Road,
Bootle,
Merseyside,
UK.
L20 1EA
Telephone: +44 (0) 151 933 7277
Email: uksales@mastgrp.com
Web: www.mast-group.com

2. Hazards identification

2.1 Classification of the substance or mixture

CLP Classification – Regulation (EC) No. 1272/2008: This product nor any of its components is not classified as hazardous.

Physical hazards: Based on available data, there are no physical hazards.

Health hazards: Based on available data, there are no overall health hazards.

Environmental hazards: Based on available data, there are no environmental hazards.

2.2 Label elements

Pictogram: None.

Signal word: None.

Hazard statements: None.

Precautionary statements: None.

2.3 Classification according to EU Directive 67/548/EEC or 1999/45/EC

Hazard symbol: None.

R-phrases(s): None.

S-phrases(s): None.

2.4 Other hazards

No information available.

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3. Composition/information on ingredients

- Composition:** A multi-component diagnostic kit, containing:
1. 8-well strip tubes containing lyophilised single-reaction amplification pellets with primers against specific CRE targets in a set orientation (ART P1-8)
 2. Lyophilised Inhibition Control DNA (CRE ICDNA)
 3. Reconstitution Buffer 3 (RB3)
 4. Molecular grade water (WTR)

Hazardous ingredients:

1. **Lyophilised 8-well strip-tubes (ART P1-8)** – A lyophilised mixture containing enzyme, DNA-binding dye, dNTPs, salts and buffering agents at specific concentrations that, when reconstituted, give the base environment for Loop-mediated isothermal amplification. These pellets also contain specific oligonucleotides at set concentrations that, when reconstituted, can amplify set CRE targets and CRE ICDNA controls under isothermal conditions.

Component	CAS-No.	EC-No.	Concentration	CLP Classification – 1272/2008/EC	Classification to – 67/548/EEC
None	N/A	N/A	N/A	N/A	N/A

2. **Lyophilised Inhibition Control DNA (CRE ICDNA)** – a lyophilised pellet of synthetic DNA at a set concentration. Once reconstituted, this can be amplified with inhibition control primers that are included in the ART P1-8 strip.

Component	CAS-No.	EC-No.	Concentration	CLP Classification – 1272/2008/EC	Classification to – 67/548/EEC
None	N/A	N/A	N/A	N/A	N/A

3. **Reconstitution Buffer 3 (RB3)** – 1.5ml of a buffered liquid solution.

Component	CAS-No.	EC-No.	Concentration	CLP Classification – 1272/2008/EC	Classification to – 67/548/EEC
None	N/A	N/A	N/A	N/A	N/A

4. **Molecular grade water (WTR)** - 1.5ml of molecular grade water.

Component	CAS-No.	EC-No.	Concentration	CLP Classification – 1272/2008/EC	Classification to – 67/548/EEC
None	N/A	N/A	N/A	N/A	N/A

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4. First-aid measures

4.1 Description of First Aid measures

General advice: Consult a physician. Show this safety data sheet to the doctor in attendance.

Eye contact: Rinse thoroughly with plenty of water for 10 to 15 minutes, also under the eyelids. Obtain medical attention if irritation persists.

Skin Contact: Wash off skin thoroughly with soap and plenty of water. Obtain medical attention if irritation persists.

Ingestion: Rinse mouth out with plenty of water. Obtain medical attention if symptoms occur.

Inhalation: Move person to fresh air. Obtain medical attention immediately if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indicate any immediate medical attention and special treatment needed

No information available.

5. Fire fighting measures

5.1 Extinguishing medium

Suitable extinguishing media: Use water spray, CO₂, foam or dry powder as the extinguisher medium.

Extinguishing media which must not be used for safety reasons: No information available

5.2 Special hazards arising from the substance or mixture

Combustible material. Thermal decomposition may lead to release of irritating gases and vapours.

5.3 Advice for firefighters

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

5.4 Additional information

No data available.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Wear appropriate protective equipment. Avoid dust formation.

6.2 Environmental precautions

Should not be released into the environment.

6.3 Methods and materials for contamination and cleaning up

Sweep up or vacuum up spillage in suitable container for disposal. Avoid dust formation.

6.4 Further information

No data available.

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7. Handling and storage

7.1 Precautions for safe handling

Avoid contact with eyes, skin and clothing. Avoid ingestion and inhalation. Always use gloves when handling this product.

7.2 Conditions for safe storage, including any incompatibilities

Store unopened kit and reagents at 2°C to 30°C. Keep tightly closed in the container provided. Protect from direct sunlight and moisture.

7.3 Specific end use(s)

This product is for laboratory use only and should only be used by suitably trained laboratory personnel.

8. Exposure controls and personal protection

8.1 Control parameters

Components with workspace control parameters: Contains no substance with occupational exposure limits.

8.2 Exposure controls

Engineering controls: No engineering protection required.

Personal protective measures:

Body protection:	Wear standard microbiology laboratory coat.
Eye/face protection:	Safety glasses with side shields conforming to EN 166.
Skin and hand protection:	Wear appropriate protective clothing such as protective gloves at all times when handling this reagent.
Respiratory protection:	Handle in a well ventilated area.

General hygiene measures: Handle in accordance with good laboratory practice.
Wash hands before breaks and at the end of the working day.

9. Physical and Chemical properties

9.1 Information on basic physical and chemical properties

Physical appearance:	The ART P1-8 and CRE ICDNA reagents are lyophilised. The RB3 and WTR reagents are liquid
Odour:	reagents.
Odour threshold:	All reagents are essentially odourless.
Colour:	No data available.
pH value:	All reagents are essentially colourless.
Melting point/freezing point:	Not applicable.
Initial boiling point/range:	No data available.
Flash point:	No data available.
Evaporation rate:	No data available.
Flammability (solid, gas):	No data available.
Explosive limits:	No data available.
Vapour pressure:	No data available.
Vapour density:	No data available.
Relative density:	No data available.
Solubility in water:	No data available.
Solubility in other solvents:	No data available.
Partition coefficient (n-octanol/water):	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
Viscosity:	No data available.
Vapour density:	No data available.
Explosive properties:	No data available.
Oxidising properties:	No data available.
	No data available.

9.2 Other information

No data available.

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10. Stability and reactivity

10.1 Reactivity

None known on information available.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

Incompatible products; Avoid heat; Avoid dust formation.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

None under normal use conditions.

11. Toxicological information

11.1 Information on toxicological effects

Overall product information: This product does not present an acute toxicity based on known or supplied information.

11.2 Toxicological data for the components

Acute toxicity: None known.

Skin corrosion/irritation: No data available.

Serious eye damage/ eye irritation: No data available.

Respiratory or skin sensitisation: No data available.

Germ cell mutagenicity: No data available.

Carcinogenicity: IARC: No component of this product is present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

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

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12. Ecological information

12.1 Toxicity

Contains no substances in any quantity likely to be hazardous to the environment or that are not degradable in waste water treatment plants.

12.2 Persistence and degradability

Expected to be biodegradable.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

None known.

12.6 Other adverse effects.

No data available.

13. Disposal considerations

Disposal considerations: Dispose of in accordance with local and national regulations.
Dispose of used and contaminated waste according to local microbiological/molecular biology waste rules.

14. Transport information

14.1 UN Number

ADR/RID: IMDG: IATA: Not dangerous for shipping

14.2 UN proper shipping name

ADR/RID: IMDG: IATA: Not dangerous for shipping

14.3 Transport hazard class(es)

ADR/RID: IMDG: IATA: Not dangerous for shipping

14.4 Packaging group

ADR/RID: IMDG: IATA: Not dangerous for shipping

14.5 Environmental hazards

ADR/RID: IMDG: IATA: None known.

14.6 Special precautions for user

No data available

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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

Chemical safety assessment reports are not required for mixtures/IVD products.

16. Other information

Original origination date: 09/09/2019

Reason for change to document: Storage temperature information changed in lie with product Instructions for Use.

The above information is believed to be correct but does not purport to be all inclusive and shall be used as a guide only. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product and is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. Mast Group Ltd. shall not be held liable for any damage resulting from handling or from contact with the above product. See our website at www.mast.grp.com and/or the reverse side of our invoice for additional terms and conditions of sale.