

# SAFETY DATA SHEET



In accordance with Regulation (EC) No 2020/878  
Revision date: 04/10/2022  
Version number: 02

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

### 1.1 Product Identifier

**Product Name:** MAST ISOPLEX® CRE-ART

**Product Code:** DNALYO5

### 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

Feldstraße 20  
23858 Reinfeld  
Germany  
Telephone: +49 4533 20 07 34  
Email: mast@mast-diagnostica.de  
Web: www.mast-group.com

### 1.4 Emergency Contact information

UK contact: Telephone: +44 (0) 151 933 7277 (8am - 5pm GMT Monday to Friday)

EU contact: Telephone: +49 4533 20 07 34 (7am - 4pm GMT Monday to Friday)

## 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.

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## 2.3 Other hazards

No information available.

### 3. Composition/information on ingredients

#### Composition:

MAST ISOPLEX<sup>®</sup>CRE-ART is a multi-component diagnostic kit, containing:

1. CRE STRIP - Lyophilised pellets containing primers in strip tubes (8 tubes per strip, each pellet contains primers to a single CRE target sequence) x 10
2. Vacuum dried Inhibition Control DNA (ICDNA) x 1
3. Reconstitution buffer (RB3) x 1
4. Water (WTR) x 1

#### Hazardous ingredients:

1. **CRE-STRIP** – Each tube of a CRE STRIP contains primer specific to a target sequence found in Carbapenemase resistant Enterobacteriales and other Carbapenem resistant bacteria as listed below.  
Tube 1: OXA-48 specific primer set  
Tube 2: OXA-23 specific primer set  
Tube 3: OXA-24/OXA-40 specific primer set  
Tube 4: KPC specific primer set  
Tube 5: VIM specific primer set  
Tube 6: NDM specific primer set  
Tube 7: IMP specific primer set  
Tube 8: Inhibition control specific primer set  
Each pellet contains a lyophilised mixture containing enzyme, dNTP's, salts, buffering agents, intercalating dye and specific target primers at specific concentrations that, when reconstituted, allow for Loop-mediated isothermal amplification (LAMP).

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. **Inhibition Control DNA (ICDNA):** Plasmid pEX-A128 with integrated randomised synthetic DNA in a vacuum dried format.

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. **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

4. **Reconstitution buffer (RB3)** – 1.5ml of 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

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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, CO<sub>2</sub>, 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 containment 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 the unopened kit at 2°C to 30°C and protect reagents from direct sunlight. Following resuspension of ICDNA the solution can be stored at 2°C to 8°C if it is to be used on the same day. For longer term storage after reconstitution, store in small aliquots at minus 20°C to prevent multiple freeze thaw cycles.

### 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 state:	CRE STRIP: Lyophilised pellets. RB3 and WTR: Liquid reagents ICDNA: Dried pellet..
Colour:	The CRE STRIP and ICDNA are white lyophilised pellets. All other elements of these kits are colourless.
Odour:	All reagents are essentially odourless.
Melting point/freezing point:	Not applicable.
Initial boiling point/range:	No data available.
Flammability:	No data available.
Lower and upper explosion limit:	No data available.
Flash point:	No data available.
Auto-ignition temperature:	No data available.
Decomposition temperature:	No data available.
pH	No data available.
Kinetic viscosity:	No data available.
Solubility in water/other solvents:	No data available.
Partition coefficient (n-octanol/water):	No data available.
Vapour pressure:	No data available.
Density/Relative density:	No data available.
Relative vapour density:	No data available.
Decomposition temperature	No data available.
Particle characteristics	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.

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.

### 11.2 Toxicological data for the components

Assess endocrine disrupting properties for human health. This product does not contain any known or suspected endocrine disruptors.

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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 Endocrine disrupting properties: requiring you to give product information on adverse effects on the environment caused by endocrine-disrupting properties

This product does not contain any known or suspected endocrine disruptors.

### 12.7 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

### 14.7 Maritime transport in bulk according to IMO instruments

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: 13/11/2019

Reason for change to document: Updated in accordance with Regulation (EC) No 2020/878

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](http://www.mast.grp.com) and/or the reverse side of our invoice for additional terms and conditions of sale.