

In accordance with Regulation (EC) No 2020/878 Revision date: 23/09/2022

Version number: 02

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

1.1 Product Identifier

Product Name: MAST® CARBA PACE. For the rapid detection of carbapenemase producing Enterobacterales,

Pseudomonas, OXA 48 and 23-like enzyme production in Acinetobacter.

Product Code: PACE-ID

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: Not hazardous

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

No information available



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3. Composition/information on ingredients

Composition:

A multi-component diagnostic kit, containing:

- 1. PEL vial. Freeze dried pellet 4 white capped vials containing inhibitors and lysis components in an inert carrier.
- 2. RB vial. Reconstitution buffer 4 blue capped vials containing chromogenic indicator resuspension buffer.
- 3. Plastic 0.5 ml tubes

Hazardous ingredients:

1. Vial PEL

Component	CAS-No.	EC-No.	Concentration	CLP Classification – 1272/2008/EC
Vancomycin	608-08-2	210-154-2	<10mg/vial	Acute Toxicity Cat. 4; Skin Irritation Cat.2; Eye Irritation Cat. 2; Specific target organ toxicity - single exposure Cat. 3; H302 - Harmful if swallowed.
				H315 - Causes skin irritation.
				H319 - Causes serious eye irritation.
				H335 - May cause respiratory irritation.
Polymyxin B	1405-20-5	215-774-7	<10mg/vial	Acute toxicity, Oral Cat. 4.
				H302 - Harmful if swallowed.
Potassium	61177-45-5	262-640-9	<1mg/vial	Flam. Sol. 2; Self-heat. 2; Water-react. 3; Eye Irritation Cat. 2; Respiratory
clavulanate				Sensitisation Cat. 1; Skin Sensitisation Cat. 1;
				H317 - May cause an allergic skin reaction.
				H319 - Causes serious eye irritation.
				H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
				EUH014 - Reacts violently with water.
				EUH044 - Risk of explosion if heated under confinement.
Cloxacillin	7081-44-9	211-390-9	<10mg/vial	Skin irritation Cat. 2; Eye irritation Cat. 2; Respiratory sensitization Cat. 1; Skin sensitization Cat. 1; Specific target organ toxicity - single exposure Cat. 3. H315 - Causes skin irritation.
				H317 - May cause an allergic skin reaction.
				H319 - Causes serious eye irritation.
				H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
				H335 - May cause respiratory irritation.

2. Vial RB

Component	CAS-No.	EC-No.	Concentration	CLP Classification – 1272/2008/EC
Succinic acid	110-15-6	203-740-4	<3% w/v	Danger Eye Dam. Cat. 1; H318 – Causes serious eye damage.

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.



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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.

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

For all tube components sweep or scoop up and arrange for disposal.

7. Handling and storage

7.1 Precautions for safe handing

Avoid contact with eyes, skin and clothing. Avoid ingestion and inhalation.

7.2 Conditions for safe storage, including any incompatabilities

Store at 2°C to 8°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.



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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 Body protection: Wear standard microbiology laboratory coat.

measures:

Eye/face protection: Safety glasses with side shields conforming to EN 166.

Skin and hand protection: Wear appropriate protective clothing e.g. nitrile gloves.

Respiratory protection: Handle in a well ventilated area.

General hygiene Handle in accordance with good laboratory practice.

measures: 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: 1. PEL vial - White capped clear glass vial containing a white freeze dried pellet.

2. RB vial - Blue capped clear glass vial containing a beige coloured liquid.

Colour: 1. PEL vial - White pellet.

2. RB vial - Beige coloured liquid.

Odour: Odourless.

Melting point/freezing point: No data available. 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. 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:
Decomposition temperature
Particle characteristics:
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
This product does not present an acute toxicity based on known or supplied information.

information:

Acute toxicity: No data available.

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: No data available.

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: No data available.

11.2 Information on other hazards

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

This product is not known 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

No data available.

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 contaminated waste, e.g. used plates, according to local microbiological rules.

14. Transport information

14.1 UN Number

ADR/RID: IMDG: None known.

IATA:

14.2 UN proper shipping name

ADR/RID: IMDG: None known.

IATA:

14.3 Transport hazard class(es)

ADR/RID: IMDG: None known.

IATA:

14.4 Packaging group

ADR/RID: IMDG: None known.

IATA:

14.5 Environmental hazards

ADR/RID: IMDG: None known.

IATA:

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: 28/01/2019

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 and/or the reverse side of our invoice for additional terms and conditions of sale.