SAFETY DATA SHEET

In accordance with Regulation (EC) No 2020/878
Revision date: 21/09/2022
Version number: 02

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

1.1 Product Identifier

Product Name: **AmpC, ESβL and Carbapenemase Detection Disc Set**

Product Code: **D72C**

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. All components present in small quantities.

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

Heath 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

3. Composition/information on ingredients

Composition: A set of cartridges with paper discs containing: Disc A - cefpodoxime; Disc B - cefpodoxime + ESβL inhibitor; Disc C - cefpodoxime + AmpC inhibitor; Disc D - cefpodoxime + ESβL inhibitor + AmpC inhibitor; Disc E - cefpodoxime + ESβL inhibitor + AmpC inducer: Disc F Penem – each in an inert carrier.

Hazardous ingredients:

Component	CAS-No.	EC-No.	Concentration	CLP Classification – 1272/2008/EC	Classification to – 67/548/EEC
Cefpodoxime	80210-62-4	-	10µg/disc	Respiratory sensitisation Cat. 1; Skin sensitisation Cat. 1; H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.	Xn Harmful. R42/43 – may cause sensitization by inhalation and skin contact.
ESBL inhibitor	61177-45-5	262-640-9	1µg/disc	Flammable solids Cat.2; Self-heating substances and mixtures Cat. 2; Respiratory sensitisation Cat. 1; Skin sensitisation Cat. 1. H228 Flammable solid. H252 Self-heating in large quantities; may catch fire. H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.	F, Xn Highly flammable, Harmful. R11 Highly flammable. R42/43 May cause sensitisation by inhalation and skin contact. R44 Risk of explosion if heated under confinement.
AmpC inhibitor	7081-44-9	211-390-9	500µg/disc	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.	Xn harmful. R36/37/38 Irritating to eyes, respiratory system and skin. R42/43 May cause sensitization by inhalation and skin contact.
AmpC inducer	33564-30-6	251-574-6	10µg/disc	H317 - may cause an allergic skin reaction	N/A

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_2, 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.

7. Handling and storage

7.1 Precautions for safe handing

Avoid contact with eyes, skin and clothing. Avoid ingestion and inhalation. Avoid dust formation. Use forceps when handling product.

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.

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:	Handle with suitable gloves conforming to EN 374. Product may be handled with forceps.
	Respiratory protection:	If required use a nuisance type particle respirator type P1 EU EN 143.
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:	6mm filter paper discs.
Colour:	White to off white coloured.
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.
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.

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:	For cefpodoxime: no data available. For AmpC inhibitor - LD50 Oral - rat - 5,000 mg/kg. Also see RTECS: XH8920000. For AmpC inducer - LD50 Oral - rat - > 10,100 mg/kg. Also see RTECS: XI0330500. For potassium clavulanate - LD50 Oral - rat - 7,936 mg/kg. Also see RTECS: RN6802700.
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 component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity:	For potassium clavulanate: Reproductive toxicity - rat – Oral. Maternal Effects: Other effects. Effects on Newborn: Growth statistics (e.g., reduced weight gain). Developmental Toxicity - rat – Intravenous. Effects on Embryo or Fetus: Fetotoxicity (except death, e.g., stunted fetus).
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:	Because of the similarity in structure of the penicillins and cephalosporins, those who are allergic to one class of agents may manifest cross-allergenicity when a member of the other class is encountered. Gastrointestinal disturbance, Increased liver enzymes. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

11.2 Information on other hazards

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

12. Ecological information

12.1 Toxicity

This product is not known to be hazardous to the environment or 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 contaminated waste, e.g. used plates, according to local microbiological 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

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: 12/04/2017

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.