

### In accordance with Regulation (EC) No 2020/878 Revision date: 20/09/2022 Version number: 04

1. Identification of the substance or preparation and the company/ undertaking		
1.1 Product Identifier		
Product Name: M/	ASTDISCS™ ID E	extended Spectrum Beta-Lactamase (ESβL) Detection Discs
Product Code: D5	52C	
1.2 Relevant identified uses of the subst	ance or mixture	and uses advised against
Recommended uses: In	vitro diagnostic pr	roduct; Laboratory chemical
Uses advised against: No	o information avail	able
1.3 Details of supplier of the product and	<u>d safety data she</u>	<u>et</u>
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: +49 (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. Hazards identification
2.1 <u>Classification of the substance or mi</u>		
CLP Classification – Regulation (EC)		Not hazardous. Any hazardous ingredients are present in very small quantities.
	ysical hazards:	Based on available data, there are no physical hazards
	Heath hazards:	Based on available data, there are no health hazards
2.2 Label elements	nental hazards:	Based on available data, there are no environmental hazards
	Pictogram:	None
	Signal word:	None
Haz	ard statements:	None
	ary statements:	None
2.3 Other hazards	,	
		No information available



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#### 3. Composition/information on ingredients

**Composition:** A set of cartridges with paper discs containing ceftazidime; ceftazidime + clavulanic acid; cefotaxime; cefotaxime + clavulanic acid; cefpodoxime; cefpodoxime + clavulanic acid - in an inert carrier.

#### Hazardous ingredients:

Component	CAS-No.	EC-No.	Concentration	CLP Classification – 1272/2008/EC	Classification to – 67/548/EEC
Ceftazidime	78439-06-2	-	30µg/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.
Cefotaxime sodium salt	64485-93-4	264-915-9	30µg/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.
Cefpodoxime sodium salt	80210-62-4	-	30µg/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.
Potassium clavulanate	61177-45-5	262-640-9	10µg/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.

#### 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, CO <sub>2</sub> , foam or dry powder as the extinguisher medium.
Ext	inguishing 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 - 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 r	equired.
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 Wash hands before breaks	good laboratory practice. and at the end of the working day.

#### 9. Physical and Chemical properties

### 9.1 Information on basic physical and chemical properties

#### 9.2 Other information

No data available.



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10. Stability and reactivity		
10.1 Reactivity		
None known on inf	formation available.	
10.2 Chemical stability		
Stable under norm	al conditions.	
10.3 Possibility of hazardous reactions		
No data available.		
10.4 Conditions to avoid		
Incompatible produ	ucts; 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 cefotaxime: LD50 Oral - rat - > 20,000 mg/kg. Also see RTECS: XI0250000. 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 cefotaxime: Developmental Toxicity - rabbit – Intravenous. Effects on Embryo or Fetus: Fetal death. 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	

### 11.2 Information on toxicological effects

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

investigated.



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	12. Ecological information		
12.1 <u>Toxicity</u>			
	Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.		
12.2 Persistence and degrada	ability		
	Expected to be biodegradable.		
12.3 Bioaccumulative potenti	al		
	No data available.		
12.4 <u>Mobility in soil</u>			
	No data available.		
12.5 <u>Results of PBT and vPv</u>	3 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 consideration	<ul> <li>Dispose of in accordance with local and national regulations.</li> <li>Dispose of contaminated waste, e.g. used plates, according to local microbiological rules.</li> </ul>		
	14. Transport information		
14.1 <u>UN Number</u>			
ADR/RID: IMDG: IATA:	Not dangerous for shipping		
14.2 <u>UN proper shipping nam</u>	<u>le</u>		
ADR/RID: IMDG: IATA:	Not dangerous for shipping		
14.3 Transport hazard class(e	25)		
ADR/RID: IMDG: IATA:	Not dangerous for shipping		
14.4 Packaging group			
ADR/RID: IMDG: IATA:	Not dangerous for shipping		
14.5 <u>Environmental hazards</u>			
ADR/RID: IMDG: IATA:	None known.		
14.6 Special precautions for user			
	No data available		
14.7 <u>Maritime transport in bu</u>	Ik 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:	03/04/2002	
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.orp.com and/or the reverse side of our invoice for additional terms and conditions of sale.	