EUCODIS

# **Data Sheet**

# LacBuster<sup>™</sup>-S

Cat. No.	Formulation	Sales Unit	Activity / vial
EB006.4	freeze dried powder	1 vial	> 50'000 IU βI > 5'000 IU βII

## Specifications

**LacBuster**<sup>TM</sup>-**S** is a  $\beta$ -lactamase formulation with a broad substrate range against  $\beta$ -lactam antibiotics including carbapenems, cephalosporins up to 5<sup>th</sup> generation, and penicillins.

LacBuster<sup>™</sup>-S is available as a freeze-dried product containing buffer salts.

## Unit definition

One International unit of Penicillinase activity (IU  $\beta$ -I) will hydrolyze 1.0 µmole benzylpenicillin per minute at pH 7.0 and 25°C. One IU  $\beta$ -I corresponds to 600 Levy Units or 100.000 Kersey Units, respectively.

One International unit of Cephalosporinase activity (IU  $\beta$ -II) will hydrolyze 1.0 µmole cephalosporin C per minute at pH 7.0 and 25°C.

# Applications

**LacBuster**<sup>TM</sup>-**S** can be applied for sterility testing of  $\beta$ -lactam antibiotics by membrane filtration according to US and European Pharmacopeia methods. It can be easily incorporated into existing standard operating procedures by addition of the reconstituted sterile-filtered enzyme solution to all buffers and media.

To validate complete inactivation of the  $\beta$ -lactam a challenge test (using less than 100 colony-forming units of *Staphylococcus aureus* ATCC 6538 or *Bacillus subtilis* ATCC 6633) with an appropriate quantity of enzyme has to be performed under the customer-specific settings. Please refer to our application specialists for further advice.

Further applications include environmental monitoring of manufacturing areas and sterility testing of blood cultures.

#### **Recommendations for use**

For reconstitution, we recommend dissolving the content of one vial EB006.4 in 40 mL of deionized, purified water. After reconstitution, filter-sterilize through a 0.2  $\mu$ m low-protein binding membrane.

For preparation of agar plates, **LacBuster**<sup>M</sup>-**S** should be added to the medium at a temperature of  $\leq 55^{\circ}$ C.

#### Sterility

**LacBuster<sup>TM</sup>-S** EB006.4 is neither pre-sterilized nor irradiated and should be filter-sterilized after reconstitution. An irradiated formulation is available as **LacBuster<sup>TM-S</sup> E**B006.1 or EB006.2.

## Storage/Stability

**LacBuster**<sup>TM</sup>-**S** is stable in unopened vials for one year from the date of manufacturing at 2-8°C. After reconstitution **LacBuster**<sup>TM</sup>-**S** is stable for at least two months at 2-8°C.

#### Substrate Range

**LacBuster**<sup>TM</sup>**-S** has been demonstrated to inactivate following  $\beta$ -lactam antibiotics efficiently:

- **Cephalosporins:** Cefaclor, Cefadroxil, Cefazolin, Cefepime, Cefixime, Cefotaxime, Cefoxitin, Cefpodoxime, Ceftazidime, Ceftibuten, Ceftriaxon, Cefuroxime, Cephalexin
- **Carbapenems:** Doripenem, Ertapenem, Imipenem, Meropenem
- **Penicillins:** Amoxicillin, Ampicillin, Benzylpenicillin, Oxacillin, Piperacillin. Ticarcillin

For *in vitro* use only.

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