SCIENCE

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# **Data Sheet**

# LacBuster<sup>™</sup>-S

Cat. No.	Formulation	Sales Unit	Activity/vial
EB006.1	freeze dried powder	10 vials	> 500 IU βI > 50 IU βII
EB006.2	freeze dried powder	1 vial	> 20000 IU βI > 2000 IU βII
EB006.7	freeze dried powder	1 vial	> 10000 IU βI > 1000 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™-S** is available as a freeze-dried product containing buffer salts (potassium phosphate, sodium chloride and sorbitol).

# Unit definition

One International unit of Penicillinase activity (IU  $\beta$ -I) will hydrolyze 1.0  $\mu$ mole 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 EB006.1 in 10 mL, or one vial of EB006.2 / EB006.7 in 40 mL of deionized, purified water. After reconstitution, filter-sterilize through a 0.2 µm low-protein binding membrane. For preparation of agar plates, **LacBuster™-S** should be added to the medium at a temperature of  $\leq$  55°C.

## Sterility

**LacBuster<sup>™</sup>-S** vials are sterilised by gammairradiation. There is no detectable growth in Tryptone Soy broth at 30-35°C for 14 days.

## Storage/Stability

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

## Substrate Range

**LacBuster**<sup>M</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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