

ORIGIN ID: VDDA 00431890080413  
VANESSA FEUERER  
EUCODIS BIOSCIENCE GMBH  
CAMPUS VIENNA BIOCENTER II  
VIEHMARKTGASSE 2A  
WIEN, 1030  
AUSTRIA, AT

Ship Date: 03JUN19  
ActWgt: 2.00 KG MAN  
CAD: 6159/141/GSMW1059  
Dims: 23x23x23 CM  
BILL SENDER  
EINWAT:

TO KERI SMITH

(405) 271-1144

ARL BIO PHARMA, INC  
D.B.A. ANALYTICAL RESEARCH LABORATO  
840 RESEARCH PARKWAY, SUITE 546  
OKLAHOMA CITY, OK 73104

FedEx  
Express



(US)

AWB

J171016102020uv

XH OKCA

PKG TYPE: CUSTOMER



TRK# 6740 7792 5534 Form 0430

INTL PRIORITY

REF: 20190065 34  
DESC1: beta-lactamase, sterile liquid, ready-to-use  
DESC2:  
DESC3:  
DESC4:

COUNTRY MFG: AT  
CARRIAGE VALUE: 0.00 EUR  
CUSTOMS VALUE: 4170.00 EUR

SIGN: VANESSA FEUERER  
T/C: S 397082164  
D/T: R

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1. Fold the printed page along the horizontal line.  
2. Place label in shipping pouch and affix it to your shipment.



EUCODIS Bioscience GmbH  
Campus Vienna Biocenter 2  
Viehmarktgasse 2a, 1030 Wien, Austria  
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www.eucodis.com

INVOICE ADDRESS

**ARL Bio Pharma, Inc**  
d.b.a. Analytical Research Laboratories  
840 Research Parkway, Suite 546  
Oklahoma City, OK 73104  
USA

DELIVERY ADDRESS

**ARL Bio Pharma, Inc**  
d.b.a. Analytical Research Laboratories  
840 Research Parkway, Suite 546  
Oklahoma City, OK 73104  
USA

**To the attention of:**  
Keri Smith

**Your Order Number:** 27597  
**Your Order Date:** 28 May 2019  
**Customer VAT ID:** —  
**Customer Code:** 201006

**Our Offer:** 20190009  
**Order Confirmation Date:** 29 May 2019  
**Our Order Confirmation:** 20190060  
**Our EORI Number:** ATEOS1000013742

**PROFORMA INVOICE for Order # 201900060**

*LacBuster™-L, 10 ml*

Pos.- No.	Product ID	Product Name	Quantity	Unit Price EUR	Total Price EUR
1	EB008.1	LacBuster™-L, liquid sterile, 10ml (1000 IU beta lactamase II/vial)	10	€ 417	€ 4,170
2	n.a.	Shipping costs	1	€ 140	€ 140
<b>Subtotal</b>					<b>€ 4,310</b>
VAT (0%), Supply, Export					-
<b>TOTAL</b>					<b>€ 4,310</b>

**FedEx tracking number:** 674077925534

**Customs tariff number:** 35079090

**Manufacturer:** EUCODIS Bioscience GmbH, Viehmarktgasse 2a, 1030 Vienna, Austria

**Country of origin:** Austria

**Secondary condition:** EXW Vienna (Incoterms 2010)  
Customs clearance costs and import taxes not included.

With kind regards

Dr. Susanne Bach



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USA

DELIVERY ADDRESS

**ARL Bio Pharma, Inc**  
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840 Research Parkway, Suite 546  
Oklahoma City, OK 73104  
USA

To the attention of:

Keri Smith

Your Order Number:

27597

Your Order Date:

28 May 2019

Customer VAT ID:

—

Customer Code:

201006

Our Offer:

20190009

Order Confirmation Date:

29 May 2019

Our Order Confirmation:

20190060

Our EORI Number:

ATEOS10000013742

**DELIVERY NOTE # 20190065**

**LacBuster™-L, 10 ml**

Shipping Date:

Vienna, 03 June 2019

Number of Packs:

1

Shipment:

FedEx

Tracking number: 674077925534

Dispatch Control:

Jennifer Lehrmann ([lehrmann@eucodis.com](mailto:lehrmann@eucodis.com))

Pos.- No.	Product ID	Product Name	Quantity
1	EB008.1	LacBuster™-L, liquid sterile, 10ml (1000 IU beta lactamase II/vial)	10

Comments:

Store at 2-8°C

## FOR REVIEW by USDA Inspector

Vienna, 2019-06-03

### Declaration of Goods according to USDA APHIS Guideline #11114

We confirm hereby that

1. the goods contained in this shipment consist of purified proteins (enzymes) produced by recombinant microorganisms (*Escherichia coli*, *Pichia pastoris*, *Aspergillus oryzae*, *Streptomyces lividans*), and buffer salts,
2. the goods contained in this shipment are non-toxic, non-hazardous, non-infectious, free of host and plasmid DNA,
3. all expression vectors used for production are NOT pathogenic for livestock or avian species AND the host organisms do NOT contain any genes or express antigens of livestock or poultry disease agents,
4. the goods contained in this shipment do NOT contain any animal derived additives,
5. the goods contained in this shipment are produced under animal-free conditions, meaning all raw materials and media used are NOT from animal origin,
6. the goods contained in this shipment are for in vitro use only.

With kind regards

A handwritten signature in black ink, appearing to read "Jan Modregger".

Dr. Jan Modregger  
Head of Research and Development,  
Head of Production

- To whom it may concern -

## MANUFACTURER DECLARATION

### EUCODIS LacBuster™-L (beta-lactamase)

*Applies to Product No.'s EB008.1*

EUCODIS LacBuster™-L is a preparation of recombinant beta-lactamase enzyme of microbial origin and contains only the polypeptide of the beta-lactamase in a sterile solution containing potassium phosphate buffer.

**The preparation of LacBuster™-L is therefore non-toxic, non-hazardous, and non-infectious and does not contain any material from animal origin.**

Beta-lactamases are highly specific enzymes which can be used for the inactivation of beta-lactam antibiotics for sterility tests and environmental monitoring during the production of beta-lactam antibiotics. To the best of our knowledge there is no secondary use application for beta lactamases according to council regulation EC 428/2009.

EUCODIS LacBuster™-L is intended for research and quality control purposes only, not for use in humans.

Identifier	<b>EB008.1</b> , recombinant microbial beta-lactamase of microbial origin CAS 9073-60-3, EC 3.5.2.6
Composition	Polypeptide of beta lactamase, potassium phosphate, sodium chloride, sterile liquid , pH of the solution: 7.0
Hazards Identification	Non-toxic, non-hazardous, and non-infectious and do not contain any material from animal origin. See also attached MSDS.
Country Origin	Austria
Usage	Inactivation of beta-lactam antibiotics for quality control and environmental monitoring.
Disposal	According to federal, state, and local environmental regulations.

The above data have been compiled to the best of our knowledge on the basis of thorough tests and with regard to our own and current state of the art experience.

EUCODIS Bioscience GmbH  
Dr. Jan Modregger  
Head of Research and Development

# Data Sheet



## LacBuster-L

Cat. No.	Formulation	Sales Unit	Activity/vial
EB008.1	Sterile liquid, ready-to-use	10 x 10 ml	> 2500 IU $\beta$ I > 1000 IU $\beta$ II

### Specifications

**LacBuster™-L** is a novel  $\beta$ -lactamase formulation with a broad substrate range against  $\beta$ -lactam antibiotics including carbapenems, cephalosporins up to 5<sup>th</sup> generation and penicillins. **LacBuster™-L** is available as a ready-to-use sterile solution.

### Unit Definition

One International unit of  $\beta$ I activity (Penicillinase) 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  $\beta$ II activity (Cephalosporinase) will hydrolyze 1.0  $\mu$ mole cephalosporin C per minute at pH 7.0 and 25°C.

### Applications

**LacBuster™-L** can be applied for sterility testing of  $\beta$ -lactam antibiotics according to US and European Pharmacopeia. Due to its high activity **LacBuster™-L** is especially well suited for the direct inoculation method but can be used as well for membrane filtration tests. It can be easily incorporated into existing standard operating procedures by addition of the provided sterile 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 custom 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.

For preparation of agar plates, **LacBuster™-L** is added to the medium at a temperature of  $\leq 50^\circ\text{C}$ .

### Sterility

**LacBuster™-L** vials are filled under aseptic conditions. No growth in Tryptic Soy broth is observed after incubation at 30–35°C for 14 days.

### Storage/Stability

**LacBuster™-L** is stable at 2–8°C for at least one year from the date of manufacturing.  
At room temperature (15–25°C) **LacBuster™-L** is stable for at least one month.

### Substrate Range

**LacBuster™-L** has been demonstrated to inactivate following  $\beta$ -lactam antibiotics efficiently:

**Carbapenems:** Doripenem, Ertapenem, Imipenem, Meropenem

**Cephalosporins:** Cefaclor, Cefadroxil, Cefazolin, Cefepime, Cefixime, Cefotaxime, Cefoxitin, Cefpodoxime, Ceftriaxime, Cefibuten, Ceftriaxon, Cefuroxime, Cephalixin

**Penicillins:** Amoxicillin, Ampicillin, Benzylpenicillin, Cloxacillin, Nafcillin, Oxacillin, Piperacillin, Ticarcillin

For *in vitro* use only.

<p><b>Eucodis Bioscience GmbH</b>  Campus Vienna Biocenter II  Viehmarktgasse 2 a  1030 Vienna  AUSTRIA</p> <p>Phone : +43 (0)-1-8900804-10  Fax : +43 (0)-1-8900804-11  E-mail: office@eucodis.com</p>	
<p><b>CERTIFICATE OF ANALYSIS</b></p>	
<p><b>Product</b>  <b>Source</b>  <b>Host</b>  <b>Product number</b>  <b>Lot number</b>  <b>Date of analysis</b>  <b>Shelf life</b>  <b>Storage temperature</b></p>	<p><b>LacBuster™-L</b>  Prokaryotic  <i>Escherichia coli</i>  EB008.1  02610119LF0515  May 20<sup>th</sup>, 2019  12 months from date of analysis  2-8°C</p>
<p><b>Results of Analysis</b></p>	
<p><b>Appearance:</b> clear yellowish liquid</p> <p><b>Activity:</b> 328 I.U./mL (beta lactamase I)  156 I.U./mL (beta lactamase II)</p> <p>One International Unit (I.U.) of beta lactamase I activity will hydrolyze 1.0 µmole benzylpenicillin per minute in phosphate buffer, pH 7.0 at 25°C. One I.U. is equivalent to 600 Levy units.</p> <p>One International Unit (I.U.) of beta lactamase II activity will hydrolyze 1.0 µmole cephalosporin C per minute in phosphate buffer, pH 7.0 at 25°C.</p>	
<p>We hereby certify that the above information is true and correct.</p>	

**EUCODIS** Bioscience GmbH  
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Tel.: +43 1 8900804  
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Dr. Axel Niebisch  
Project Leader

## SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006  
Revision Date 07.09.2010  
Print Date 07.09.2010

GENERIC EU MSDS – NO COUNTRY SPECIFIC DATA

### 1. Identification of the Substance/Mixture and of the Company/Undertaking

Product Name: EUCODIS LacBuster™-L, microbial , recombinant from E. coli  
Product Number: EB008

Company: Eucodis Bioscience GmbH  
Campus Vienna Biocenter II  
Viehmarktgasse 2 a/2. OG  
A-1030 Vienna AUSTRIA

Telephone : +43 (0)-1-8900804-10  
Fax : +43 (0)-1-8900804-11  
Emergency Phone: +43 (0)-1-8900804-10  
Email: [office@eucodis.com](mailto:office@eucodis.com)

### 2. Hazards Identification

#### Classification of the substance or mixture

Not a dangerous substance according to GHS.  
Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC.

#### Label elements

Caution - substance not yet tested completely.

Other hazards - none

### 3. Composition/Information on Ingredients

CAS-No.	EC-No.	Index-No	Classification	Concentration
beta lactamase				
---	3.5.2.6.	---	---	< 1%
potassium phosphate, monobasic				
7778-77-0	----	---	---	< 5%
sodium chloride				
7647-14-5	----	---	---	< 5%

### 4. First Aid Measurements

#### General

No general measures necessary.

#### If inhaled

If breathed in, move person into fresh air. If not breathing give artificial respiration

#### In case of skin contact

Wash off with soap and plenty of water.

#### In case of eye contact



<b>Safety data</b>	
pH	6.0 – 7.0
Melting point	no data available
Boiling point	no data available
Flash point	no data available
Ignition temperature	no data available
Lower explosion limit	no data available
Upper explosion limit	no data available
Water solubility	soluble
<b>10. STABILITY AND REACTIVITY</b>	
<b>Storage stability</b>	Stable under recommended storage conditions.
<b>Conditions to avoid</b>	Heat.
<b>Materials to avoid</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Hazardous decomposition products formed under fire conditions. Nature of decomposition products not known.
<b>11. TOXICOLOGICAL INFORMATION</b>	
<b>Acute toxicity</b>	no data available
<b>Skin corrosion/irritation</b>	no data available
<b>Serious eye damage/eye irritation</b>	no data available
<b>Respiratory or skin sensitization</b>	no data available
<b>Germ cell mutagenicity</b>	no data available
<b>Carcinogenicity</b>	IARC: 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.
<b>Reproductive toxicity</b>	no data available
<b>Specific target organ toxicity - single exposure</b>	no data available
<b>Specific target organ toxicity - repeated exposure</b>	no data available
<b>Aspiration hazard</b>	no data available
<b>Potential health effects</b>	
<b>Inhalation</b>	May be harmful if inhaled. May cause respiratory tract irritation.

# TOXIC SUBSTANCE CONTROL ACT (TSCA)

## CERTIFICATION

DATE: 3rd June 2019

(CHECK ONE SECTION ONLY)

### POSITIVE CERTIFICATION:

X "I CERTIFY THAT ALL CHEMICAL SUBSTANCES IN THIS SHIPMENT COMPLY WITH ALL APPLICABLE RULES OR ORDERS UNDER TSCA AND THAT I AM NOT OFFERING A CHEMICAL SUBSTANCE FOR ENTRY IN VIOLATION OF TSCA OR ANY APPLICABLE RULE OR ORDER THEREUNDER."

. OR .

### NEGATIVE CERTIFICATION:

"I CERTIFY THAT ALL CHEMICALS IN THIS SHIPMENT ARE NOT SUBJECT TO TSCA."

COMPANY NAME: Eucodis Bioscience

COMPANY ADDRESS: Viehmarktgasse 2a/2.OG 1030 Wien, Austria

AUTHORIZED NAME: Jan Modregger, PhD EUCODIS

AUTHORIZED SIGNATURE: [Signature]  
Viehmakktgasse 2a  
1030 Wien, Österreich  
Tel.: +43-1-80095904  
www.eucodis.com

TITLE: Head of Research & Development

FEDERAL EXPRESS AWB#: 674077924939

RETURN TO: ---

IF THE CERTIFIER IS UNSURE IF THEIR CHEMICAL SUBSTANCE IS SUBJECT TO TSCA COMPLIANCE, CONTACT THE ENVIRONMENTAL PROTECTION AGENCY, TSCA ASSISTANCE OFFICE, WASHINGTON, D.C. (202) 554-1404 BETWEEN 8:30 AM AND 5:00 PM EST.

REVISED May 7, 1990