

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: 6159141/GSMW1059
Dims: 23x23x23 CM
BILL SENDER
EIN/VAT:

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

(US)

FedEx
Express



AWB

XH OKCA



TRK# 6740 7792 5534

Form
0430

PKG TYPE: CUSTOMER

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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2. Place label in shipping pouch and affix it to your shipment.



EUCODIS Bioscience GmbH
Campus Vienna Biocenter 2
Viehmarktgasse 2a, 1030 Wien, Austria
Tel: +43 1 8900804-10 Fax: +43 1 8900804-11
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 # 20190060

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
Subtotal					€ 4,310
VAT (0%), Supply, Export					-
TOTAL					€ 4,310

FedEx tracking number: 674077925534

Customs tariff number: 35079090

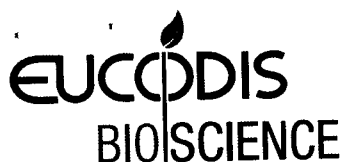
Manufacturer: EUCODIS Bioscience GmbH, Viehmarktgasse 2a, 1030 Vienna, Austria

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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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

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)

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 #1114

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



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	EB008.1 , 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



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

Specifications

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

Unit Definition

One International unit of β I activity (Penicillinase) will hydrolyze 1.0 μ mole benzylpenicillin per minute at pH 7.0 and 25°C. One IU β I corresponds to 600 Levy units or 100.000 Kersey Units, respectively.

One International unit of β II activity (Cephalosporinase) will hydrolyze 1.0 μ mole cephalosporin C per minute at pH 7.0 and 25°C.

Applications

LacBuster™-L can be applied for sterility testing of β -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 β -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 β -lactam antibiotics efficiently:

Carbapenems: Doripenem, Ertapenem, Imipenem, Meropenem

Cephalosporins: Cefaclor, Cefadroxil, Cefazolin, Cefepime, Cefixime, Cefotaxime, Cefoxitin, Cefpodoxime, Ceftazidime, Ceftibuten, Ceftriaxon, Cefuroxime, Cephalexin

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

For *in vitro* use only.

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1030 Vienna
AUSTRIA
Phone : +43 (0)-1-8900804-10
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E-mail: office@eucodis.com

CERTIFICATE OF ANALYSIS

Product	LacBuster™-L
Source	Prokaryotic
Host	<i>Escherichia coli</i>
Product number	EB008.1
Lot number	02610119LF0515
Date of analysis	May 20 th , 2019
Shelf life	12 months from date of analysis
Storage temperature	2-8°C

Results of Analysis

Appearance: clear yellowish liquid

Activity: 328 I.U./mL (beta lactamase I)
156 I.U./mL (beta lactamase II)

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.

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.

We hereby certify that the above information is true and correct.

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Viehmarktgassee 2a
1030 Wien, Österreich
Tel.: +43 1 890 08 04
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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

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

Safety data

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

10. STABILITY AND REACTIVITY**Storage stability**

Stable under recommended storage conditions.

Conditions to avoid

Heat.

Materials to avoid

Strong oxidizing agents.

Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. Nature of decomposition products not known.

11. TOXICOLOGICAL INFORMATION**Acute toxicity**

no data available

Skin corrosion/irritation

no data available

Serious eye damage/eye irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

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.

Reproductive toxicity

no data available

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

Inhalation	May be harmful if inhaled. May cause respiratory tract irritation.
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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: Viehmarktgassee 2a/2.OG 1030 Wien, Austria

AUTHORIZED NAME: Jan Modregger, PhD

AUTHORIZED SIGNATURE: [Signature]

TITLE: Head of Research & Development

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www.eucodis.com

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