

Information about non-hazardous mixture

Product name: PharmaBio Burkholderia (BCSA) Agar; PharmaBio Burkholderia (BCSA) Agar Plus

Product code(s): PBUA20100, PBUA20500, PBUA25000, PBUA210000, PBUA225000, PBUA30100, PBUA30250, PBUA30500, PBUA50055, PBUA50065, PBUA50090

Product type: mixture

Physicochemical properties:

- Colour:	dehydrated media:	Yellowish
	prepared media:	Orange
- pH:	dehydrated media:	6,9-7,3
	prepared media:	7,0-7,2

Manufacturer:

- Name:	Biolab Zrt.
- Address:	Öv street 43., 1141 Budapest, Hungary
- Telephone:	+36-1-221-96-14
- e-mail:	SDS@biolab.hu
- Website:	www.biolab.hu

Emergency telephone number:

Health Toxicological Information Service (ETTSz), Postal address: 1097 Budapest, Albert Flórián út 2-6., Hungary, Tel. +36-80-201-199 (free, day and night) +36-1-476-6464 (day and night).

Classification of the substance or mixture:

Not a hazardous substance or mixture according to Regulation (EU) No 2020/878. This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

Attention.

In the case of the units of packaging PharmaBio Burkholderia (BCSA) Agar, the component no. 2 Burkholderia Selective Supplement is qualified as hazardous mixture and its safety data sheet can be found in a further document.

This certificate was issued electronically and is valid without signature.

Creation date: 2024.08.20.

SAFETY DATA SHEET

according to Commission Regulation (EU) 2020/878 as amended



PharmaBio Burkholderia (BCSA) Agar Component No. 2; Burkholderia Selective Supplement

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Version

1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Substance / mixture

Number

UFI

PharmaBio Burkholderia (BCSA) Agar Component No. 2; Burkholderia Selective Supplement

mixture

PBUA

KU60-T0W8-D00A-YE62

1.2. Relevant identified uses of the substance or mixture and uses advised against Mixture's intended use

For microbiological use only.

Main intended use

PC-TEC-19

Reagents and laboratory chemicals

Mixture uses advised against

The product should not be used in ways other than those referred in Section 1.

1.3. Details of the supplier of the safety data sheet

Distributor

Name or trade name

Address

Phone

E-mail

Web address

Biolab Zrt.

Öv utca 43., Budapest, 1141

Hungary

+36-1-221-9614

SDS@biolab.hu

www.biolab.hu

Manufacturer

Name or trade name

Address

Phone

E-mail

Web address

Biolab Zrt.

Öv utca 43., Budapest, 1141

Hungary

+36-1-221-9614

SDS@biolab.hu

www.biolab.hu

Competent person responsible for the safety data sheet

Name

E-mail

Biolab Zrt.

SDS@biolab.hu

1.4. Emergency telephone number

European emergency number: 112

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification of the mixture in accordance with Regulation (EC) No 1272/2008

The mixture is classified as dangerous.

Skin Sens. 1, H317

Resp. Sens. 1, H334

Most serious adverse effects on human health and the environment

May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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2.2. Label elements

Hazard pictogram



Signal word

Danger

Hazardous substances

Gentamicin, sulfate (salt)
Vancomycin hydrochloride

Hazard statements

H317

May cause an allergic skin reaction.

H334

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements

P261

Avoid breathing dust.

P280

Wear protective gloves.

P304+P340

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P333+P313

If skin irritation or rash occurs: Get medical advice/attention.

P342+P311

If experiencing respiratory symptoms: Call a doctor.

P362+P364

Take off contaminated clothing and wash it before reuse.

2.3. Other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended. Dust may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture.

Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
CAS: 1405-20-5 EC: 215-774-7	Polymyxin B, sulfate (salt)	14.3	Acute Tox. 4, H302	
CAS: 1405-41-0 EC: 215-778-9	Gentamicin, sulfate (salt)	2.3	Skin Sens. 1, H317 Resp. Sens. 1, H334	
CAS: 1404-93-9 EC: 604-193-8	Vancomycin hydrochloride	0.5	Skin Sens. 1, H317	

Full text of all classifications and hazard statements is given in the section 16.

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SECTION 4: First aid measures

4.1. Description of first aid measures

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet. If unconscious, put the person in the stabilized (recovery) position on his side with his head slightly bent backwards and make sure that airways are free; never induce vomiting. If the person vomits by himself, make sure that the vomit is not inhaled. In life threatening conditions first of all provide resuscitation of the affected person and ensure medical assistance. Respiratory arrest - provide artificial respiration immediately. Cardiac arrest - provide indirect cardiac massage immediately.

If inhaled

Terminate the exposure immediately; move the affected person to fresh air. Protect the person against growing cold. Provide medical treatment if irritation, dyspnoea or other symptoms persist.

If on skin

Remove contaminated clothes. Wash the affected area with plenty of water, lukewarm if possible. Soap, soap solution or shampoo should be used if there is no skin injury. Provide medical treatment if skin irritation persists.

If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person. Rinsing should continue at least for 10 minutes.

If swallowed

Rinse out the mouth with clean water. In the event of issues, find medical help.

4.2. Most important symptoms and effects, both acute and delayed

If inhaled

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

If on skin

May cause an allergic skin reaction.

If in eyes

Not expected.

If swallowed

Irritation, nausea.

4.3. Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist.

Unsuitable extinguishing media

Water - full jet.

5.2. Special hazards arising from the substance or mixture

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with a chemical protection suit only where personal (close) contact is likely. Use a self-contained breathing apparatus and full-body protective clothing. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Do not inhale dust. Prevent contact with skin and eyes.

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6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

6.3. Methods and material for containment and cleaning up

Place the product mechanically in an appropriate manner. Dispose of the collected material according to the instructions in the section 13.

6.4. Reference to other sections

See the Section 7, 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Do not inhale dust. Prevent contact with skin and eyes. Contaminated work clothing should not be allowed out of the workplace. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose.

Storage temperature

min 2 °C, max 8 °C

7.3. Specific end use(s)

A selective mixture for the isolation of Burkholderia cepacia complex

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The mixture contains no substances for which occupational exposure limits are set.

8.2. Exposure controls

Take off contaminated clothing and wash before reuse. Follow the usual measures intended for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation. Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

Eye/face protection

It is not needed.

Skin protection

Hand protection: Protective gloves resistant to the product. Contaminated skin should be washed thoroughly.

Respiratory protection

Half-mask with anti-dust filter when the exposition limits of substances are exceeded or in the location with insufficient ventilation. In case of inadequate ventilation wear respiratory protection.

Thermal hazard

Not available.

Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	solid
Colour	white
Odour	data not available
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	data not available
Lower and upper explosion limit	data not available
Flash point	data not available
Auto-ignition temperature	data not available
Decomposition temperature	data not available

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pH	6-7 (undiluted)
Kinematic viscosity	data not available
Solubility in water	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

not available

SECTION 10: Stability and reactivity

10.1. Reactivity

When used in the standard way, there is not any dangerous reaction with other substances.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Unknown.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents.

10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

No toxicological data is available for the mixture.

Acute toxicity

Based on the available data, the criteria for classification of the mixture are not met. Data for the components of the mixture are not available.

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Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	3497 mg/kg				Calculation of value

Skin corrosion/irritation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Serious eye damage/irritation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Respiratory or skin sensitisation

May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Data for the components of the mixture are not available.

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Germ cell mutagenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Carcinogenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Reproductive toxicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Toxicity for specific target organ - single exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Toxicity for specific target organ - repeated exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Aspiration hazard

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

11.2. Information on other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 12: Ecological information

12.1. Toxicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

12.2. Persistence and degradability

No data are available for either the mixture or the components.

12.3. Bioaccumulative potential

No data are available for either the mixture or the components.

12.4. Mobility in soil

No data are available for either the mixture or the components.

12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7. Other adverse effects

Not available.

SECTION 13: Disposal considerations

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13.1. Waste treatment methods

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

SECTION 14: Transport information

14.1. UN number or ID number

not subject to transport regulations

14.2. UN proper shipping name

not relevant

14.3. Transport hazard class(es)

not relevant

14.4. Packing group

not relevant

14.5. Environmental hazards

not relevant

14.6. Special precautions for user

Reference in the Sections 4 to 8.

14.7. Maritime transport in bulk according to IMO instruments

not relevant

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

15.2. Chemical safety assessment

not available

SECTION 16: Other information

A list of standard risk phrases used in the safety data sheet

- | | |
|------|--|
| H302 | Harmful if swallowed. |
| H317 | May cause an allergic skin reaction. |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |

Guidelines for safe handling used in the safety data sheet

- | | |
|-----------|--|
| P261 | Avoid breathing dust. |
| P280 | Wear protective gloves. |
| P304+P340 | IF INHALED: Remove person to fresh air and keep comfortable for breathing. |

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P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P342+P311 If experiencing respiratory symptoms: Call a doctor.

P362+P364 Take off contaminated clothing and wash it before reuse.

Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

Key to abbreviations and acronyms used in the safety data sheet

Acute Tox.	Acute toxicity
ADR	European agreement concerning the international carriage of dangerous goods by road
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
EC	Identification code for each substance listed in EINECS
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union
EuPCS	European Product Categorisation System
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
log Kow	Octanol-water partition coefficient
OEL	Occupational Exposure Limits
PBT	Persistent, bioaccumulative and toxic
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
Resp. Sens.	Respiratory sensitization
RID	Agreement on the transport of dangerous goods by rail
Skin Sens.	Skin sensitization
UN	Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
VOC	Volatile organic compounds
vPvB	Very persistent and very bioaccumulative

Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

Recommended restrictions of use

not available

Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

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More information

Classification procedure - calculation method.

Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.