

SABOURAUD DEXTROSE BROTH, PH EUR - USP

A sterility test medium for the detection yeast and moulds according to PH EUR (Sabouraud Dextrose Broth – Harmonised).



Dehydrated media	
Code number:	500 g: SDB20500, 5 kg: SDB25000
Colour:	Yellowish
Appearance:	Homogeneous powder
pH before autoclaving (25 °C):	5,5 – 5,9

Direction: Suspend **30 g** in one litre of distilled water and heat gently to dissolve the medium completely.

Dispense into final containers and sterilise by autoclaving at 121 °C for 15 minutes.

Prepared media	
Bottled media:	100 ml: SDB30100, 500 ml: SDB30500
Tubed media:	150 x 15 mm: SDB40010 (10 ml)
Colour:	Brownish
pH (25 °C):	5,6 – 5,8

Direction: Dispense the bottled media aseptically into sterile final container. Media in tubes are ready to use.

FORMULA in g/l

Casein peptone	5
Meat peptone	5
Glucose	20

Note: The typical formula can be adjusted to obtain optimal performance.

Storage conditions: Store the dehydrated media tightly closed in a dry place at room temperature. Store the bottled and tubed media protected from light at room temperature. Use before the expiry date on the label.

Quality control:

Test strains	Incubation temp: 25 °C	Growth	Incubation time: 48 h
<i>Candida albicans</i>	ATCC 10231	Good	
<i>Aspergillus brasiliensis</i>	ATCC 16404	Good	

References: European Pharmacopoeia

In vitro diagnostic – for professional use only!

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 REACH) and 1272/2008 EK (CLP-GHS)

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifiers

Product name (dehydrated media): Sabouraud Dextrose Broth, PH EUR - USP
Product name (ready to use media): Sabouraud Dextrose Broth, PH EUR - USP
Code number: SDB
Registration number: -
CAS number: -

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Microbiological diagnostics
Uses advised against: No information available

1.3 Details of the supplier of the safety data sheet

Manufacturer/distributor: BIOLAB Inc.
H-1141 Budapest, Öv u. 43.
Hungary
Telephone: +36-1-221-9614
Fax: +36-1-364-2006
E-mail: export@biolab.hu

1.4 Emergency telephone number

Emergency telephone: Please contact the regional Authority in your country.

2. HAZARDS IDENTIFICATION

2.1 Classification of substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.
Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC.

2.2 Label elements

Labelling in accordance with Regulation (EU) No. 1272/2008:

Signal word: -
Hazard Statements (H phrases): -
Precautionary Statements (P phrases): -
Pictograms: -

2.3 Other hazards

No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

3.2 Mixtures

It is not necessary to publish the components.

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4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice:	Consult a physician. Show the label and this safety data sheet to the doctor in attendance. Never administer anything orally to persons who are unconscious.
After inhalation:	Remove the victim from exposure and move into open air. Consult a physician.
After skin contact:	Remove contaminated clothing. Flush the skin with water, then wash thoroughly with soap and water.
After eyes contact:	Rinse out eyes with plenty of clean and cold water while pulling eyelids up, and seek medical assistance.
After ingestion:	Rinse the mouth with water and seek immediate medical attention. Never administer anything orally to persons who are unconscious. Never induce vomiting.

4.2 Most important symptoms and effect, both acute and delayed

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

4.3 Indication of any immediate medical attention and special treatment needed

No information available

5. FIRE FIGHTING MEASURES

5.1 Suitable extinguishing media

Use water spray, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

In case of fire: Carbon-oxides, nitrogen oxides.

Thermal decomposition can lead to release of irritating gases and vapore.

5.3 Advice for fire-fighters

Wear self contained breathing equipment for firefighting.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid generation of dusts; do not inhale dusts. Provide appropriate exhaust ventilation. Use personal protective clothing.

6.2 Environmental precautions

Prevent the contamination of drains, surface or subterranean waters, and the ground.

6.3 Methods and material for containment and cleaning up

Take up dry. Keep in suitable, closed containers for disposal. Clean up affected area.

6.4 Reference to other sections

Refer to protective measures listed in Section 8 and 13.

SAFETY DATA SHEET

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7. HANDLING AND STORAGE

7.1 Precautions for safe handling

No special requirement.

Avoid direct contact with the material, spillage, ingestion, eye and skin contact, inhalation. No eating and smoking during working. In the application area, smoking, eating and drinking must be prohibited. Bathing facilities with hot water, emergency douche and eye irrigator have to be ensured. Wash hands after working with the product.. Remove contaminated clothing.

7.2 Conditions for safe storage, including any incompatibilities

Store the dehydrated media tightly closed in a dry place at room temperature. Store the bottled and tubed media protected from light at room temperature.

7.3 Specific end use(s)

Use in laboratories.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

The product does not contain substances with Professional Exposure Environmental Limit Values.

Exposure limits

Allowable workplace concentration (AK) (mg/m³): No information available

Workplace peak concentration: (CK) mg/m³: No information available

Biological exposure: No information available

8.2 Exposure controls

General instructions

Avoid direct contact with the material, spillage, ingestion, eye and skin contact, inhalation. No eating and smoking during working. Bathing facilities with hot water, emergency douche and eye irrigator have to be ensured. Wash hands after working with the supplement. Remove contaminated clothing.

Personal protection: Wear protection clothing, remove the contaminated clothing. Wash hands after working with the substance.

Personal protection equipment: respirator required (type P1) when dusts are generated

Eye protection: safety glasses are required

Hand protection: use disposable gloves (nitrile caoutchouc 0,11 mm, breakthrough time 0,11 mm, breakthrough time 480 min.

and wash hands after working with this substance

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance (dehydrated medium): Homogeneous hygroscopic powder

Colour (dehydrated medium): Yellowish

Odor (dehydrated medium): No information available

pH before autoclaving (25 °C): 5,7 approx.

Appearance (ready to use medium): Broth

VERSION: 2

CREATION DATE: 07/05/2013

REVISION DATE: 05/05/2016

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according to Regulation (EC) No. 1907/2006 REACH) and 1272/2008 EK (CLP-GHS)

Colour (ready to use medium):	Brownish
Odor (ready to use medium):	No information available
pH (ready to use medium, 25 °C):	5,0 – 5,2
Water solubility:	> 30 g/l
Odor threshold:	No information available
Melting point/range:	No information available
Flash point:	No information available
Evaporation rate:	No information available
Flammability (solid, gas):	No information available
Flammability range:	No information available
Vapor pressure:	No information available
Vapor density:	No information available
Relative density:	No information available
Partition coefficient (n-octanol/water):	No information available
Autoignition temperature:	No information available
Decomposition temperature:	No information available
Viscosity:	No information available
Explosive properties:	No information available
Oxidizing properties:	No information available

9.1 Other information

No information available

10. STABILITY AND REACTIVITY

10.1 Reactivity

No information available

10.2 Chemical stability

Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

No information available

10.4 Conditions to avoid

Strong heating, in case of powdered media: risk of powder explosion.

10.5 Incompatible materials

No information available

10.6 Hazardous decomposition products

See details in section 5.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	No information available
Skin irritation/corrosion:	No information available
Serious eye damage/irritation:	No information available

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Respiratory or skin sensitization:	No information available
Germ cell mutagenicity:	No information available
Carcinogenicity:	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 information available
STOT – single exposure:	No information available
STOT – repeated exposure:	No information available
Aspiration hazard:	No information available

12. ECOLOGICAL INFORMATIONS

12.1 Toxicity

No information available

12.2 Persistence and degradability

No information available

12.3 Bioaccumulative potential

No information available

12.4 Mobility in soil

No information available

12.5 Results of PBT and vPvB assessment

No information available

12.6. Other adverse effects

Do not dispose of the residue into water, sewage or soil.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods Product:

Residue is classified as hazardous.

Contaminated packaging: Handle contaminated empty packaging in the same way as the substance itself.

Waste treatment regulations: Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.

14. TRANSPORT INFORMATION

14.1 UN-number

ADR/RID: -

IMDG:-

IATA:-

14.2 UN proper shipping name

ADR/RID:

Not dangerous goods

IMDG:

Not dangerous goods

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IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: no IMDG: no IATA: no

14.4 Packaging

ADR/RID: no IMDG: no IATA: no

14.5 Environmental Hazards

ADR/RID: no IMDG: no IATA: no

14.6 Special precautions for user

No special precautions required

14.7 Transport in bulk according to Annex II of MARPOL and the IBC code

Not applicable,
packaged goods

15. REGULATORY INFORMATION

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

Regulation (EC) No 1907/2006 (REACH) and 1272/2008 EK (CLP-GHS)

15.2 Chemical safety assessment

There has been no evaluation a chemical safety assessment of the product.

During recent review the Safety Data Sheet was revised completely. The information in this Safety Data Sheet is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.

QUALITY CONTROL CERTIFICATE

MINŐSÉGI BIZONYÍTVÁNY

Sabourad Dextrose Broth, PH EUR - USP	
Sabouraud dextróz leves, PH EUR - USP	
Catalogue number: Katalógus szám:	SDB20500
Packaging (in case of KITS only): Csomagolás (csak KIT-ek esetén):	-
Lot: Lot:	SDB241017052
Manufacture date: Gyártási dátum:	2017. október 24. / 24-10-2017
Expiry: Lejárat:	2020. október / 10-2020

PHYSICAL CONTROL					
Fizikai ellenőrzés					
Dehydrated Media Portáptalaj	Criteria Előírás			Result Eredmény	
Colour: Szín:	Yellowish Sárgás			Conform Megfelel	
Appearance Megjelenés:	Homogeneous powder Homogén por			Conform Megfelel	
Prepared Media Készítáptalaj	Sterilization: Sterilizálás:	121 °C 15 min	Supplement Kiegészítő:		
Directions Bemérés: 30 g/l					
	Colour Szín	Clarity Tisztaság	Deposit Üledék	Gel strength Gélerősség	Result Eredmény
Bottled Media Készítáptalaj	Brownish Barnás	Transparent Transzparens	None Mentes	.	ile gél erő
Tubed Media Csöves táptalaj	Brownish Barnás	Transparent Transzparens	None Mentes	.	
Lemeztáptalaj	



CHEMICAL CONTROL		
Kémiai ellenőrzés		
Prepared Media	Criteria	Result
Készítáptalaj:	Előírás	Eredmény
pH before autoclaving (25 °C)	5,7 +/- 0,2	5,7
pH autoklávozás előtt (25 °C-on)		

MICROBIOLOGICAL CONTROL		
Mikrobiológiai ellenőrzés		
Control strains	Incubation temperature:	Incubation time:
Teszt törzsek	Inkubációs hőmérséklet:	Inkubációs idő:
	25 °C	48 h
<i>Candida albicans</i> ATCC 10231	Good growth Jó növekedés	Conform Megfelel
<i>Aspergillus brasiliensis</i> ATCC 16404	Good growth Jó növekedés	Conform Megfelel

Hereby we declare:

This product has been tested by Quality Control Laboratory and conforms to the specification contained in the relevant catalogue or to the specification agreed with the customer. This product was manufactured by Biolab Inc.

Under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices". All the supporting documents, as required by Annex III on the 98/79/EC Directive, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer.

Kijelentjük, hogy

Kizárólagos felelősséget vállalunk, hogy a fenti termék megfelel az EU 98/79 - es In vitro diagnosztikai orvostechnikai eszközökről szóló direktívájában foglalt valamennyi rendelkezésének. Az ezt alátámasztó dokumentáció, amint azt a direktíva III. sz. függeléke megköveteli az I. sz. függelékben felsorolt elsődleges követelményeknek való megfelelés bizonyítása céljából, a gyártónál elérhető.

A terméket a minőségellenőrző laboratórium a fent előírt követelményeknek megfelelőeknek találta. A termék gyártója a BIOLAB Zrt.

This certificate was issued electronically and is valid without signature.

Ez egy elektronikusan készült bizonylat, mely aláírást nem igényel.

