biolab **TECHNICAL SHEET** IVD CE

PLATE COUNT AGAR

A standard medium for the enumeration of total viable micro-organisms ac-cording to ISO 4833.

Dehydrated media	
Code number:	500 g: PCA20500, 5 kg: PCA25000
Colour:	Yellowish
Appearance:	Homogeneous hygroscopic powder
pH before autoclaving (25 °C):	6,8 - 7,2

Direction: Suspend **23,5 g** in one litre of distilled water and heat with frequent agitation until the medium boils well. Sterilise by autoclaving at 121 °C for 15 minutes.

Prepared media	
Bottled media:	100 ml: PCA30100, 500 ml: PCA30500
Plated media:	55 mm: PCA50055, 90 mm: PCA50090
Colour:	Yellowish
pH (25 °C):	6,9 – 7,1

Direction: Dispense the melted bottled media aseptically into sterile Petri-dishes. Media in Petri-dishes are ready to use.

FORMULA in g/l

Casein peptone	5,0
Yeast extract	2,5
Glucose, anhydrous	1,0
Agar	15,0

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 media protected from light at room temperature. Store the plated media protected from light at 2-8 °C. Use before the expiry date on the label.

Quality control:

Test strains	Incubation temp: 37 °C	**Growth**	Incubation time: 24 h
Escherichia coli	ATCC 8739	Good	
Bacillus subtilis	ATCC 6633	Good	
Staphylococcus aureus	ATCC 25923	Good	

References: ISO 4833-1:2013(E)

In vitro diagnostic – for professional use only!

SAFETY DATA SHEET

according to Regulation (EC) No. 2015/830

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

1.1 Product identifiers

Product name (dehydrated media): **Plate Count Agar**
Product name (ready to use media): **Plate Count Agar**
Code number: **PCA**
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.

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.

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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.

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 media protected from light at room temperature. Store the plated media protected from light at 2-8 °C.

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 chlothing. 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): 7,0 approx.
Appearance (ready to use medium): Gel
Colour (ready to use medium): Yellowish
Odor (ready to use medium): No information available
pH (ready to use medium, 25 °C): 6,9 – 7,1
Water solubility: > 23,5 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

9.2 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 section7).

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
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.

SAFETY DATA SHEET

according to Regulation (EC) No. 2015/830

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
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.

This document is produced electronically and is valid without signature.

CREATION DATE: 19/05/2012 REVISION DATE:

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QUALITY CONTROL CERTIFICATE

MINŐSÉGI BIZONYÍTVÁNY

Plate Count Agar Plate count (TGE) agar	
Catalogue number: Katalógus szám:	**PCA20500**
Packaging (in case of KITs only): Csomagolás (csak KIT-ek esetén):	**-**
Lot: Lot:	**PCA090218089**
Manufacture date: Gyártási dátum:	**2018. február 09. / 09-02-2018**
Expiry: Lejárat:	**2021. február / 02-2021**

PHYSICAL CONTROL

Fizikai ellenőrzés

Dehydrated Media Portáptalaj	**Criteria** Előírás	**Result** Eredmény
Colour: Szín:	**Yellowish** Sárgás	**Conform** Megfelel
Appearance Megjelenés:	**Homogeneous hygroscopic powder** Homogén nedvszívó por	**Conform** Megfelel

Prepared Media Késztáptalaj	**Sterilization:** Sterilizálás:	**121 °C** **15 min**	**Supplement** Kiegészítő:	. . .

Directions
Bemérés: **23,5 g/l**

	Colour Szín	**Clarity** Tisztaság	**Deposit** Üledék	**Gel strength** Gélerősség	**Result** Eredmény
Bottled Media Késztáptalaj	**Yellowish** Sárgás	**Transparent** Transzparens	**None** Mentes	**Suitable for good inoculation** Jól inokulálható	Megf elel
Plated Media **Tubed Media** Csöves táptalaj	**Yellowish** .	**Transparent** .	**None** .	**Suitable for good inoculation** .	
Lemeztáptalaj	Sárgás	Transzparens	Mentes	Jól inokulálható	

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CHEMICAL CONTROL

Kémiai ellenőrzés

Prepared Media Késztáptalaj:	**Criteria** Előírás	**Result** Eredmény
pH before autoclaving (25 °C) pH autoklávozás előtt (25 °C -on)	**7 +/- 0,2**	**7,0**

MICROBIOLOGICAL CONTROL

Mikrobiológiai ellenőrzés

Control strains Teszt törzsek	**Incubation temperature:** Inkubációs hőmérséklet: **37 °C**	**Incubation time:** Inkubációs idő: **24 h**
Escherichia coli *ATCC 25922*	**Good growth** Jó növekedés	**Conform** Megfelel
Staphylococcus aureus *ATCC 29213*	**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.