biolab **TECHNICAL SHEET** IVD CE

BRILLIANT GREEN AGAR BASE, HUMAN

A selective and differentiation medium for the isolation of *Salmonella* spp. (including *S. typhi*) from clinical specimens.

Dehydrated media	
Code number:	500 g: BGH20500, 5 kg: BGH25000
Colour:	Beige
Appearance:	Homogeneous hygroscopic powder
pH before autoclaving (25 °C):	7,1 – 7,5

Direction: Suspend **21,5 g** in 500 ml of distilled water and heat with frequent agitation until the medium boils well. Sterilise by autoclaving at 121 °C for 15 minutes. Cool to 50 °C and add aseptically **10 drops (0,5 ml) Brilliant Green Solution, Sterile (BGS80030-1D)**. Mix well before pouring.

Prepared media	
Bottled media bases:	100 ml: BGH30100, 500 ml: BGH30500
Plated media:	55 mm: BGH50055, 90 mm: BGH50090
Colour of bottled media:	Pink
Colour of plated media:	Bluish
pH (25 °C):	7,2 – 7,4

Direction: Supplement the melted bottled media bases according to the direction of the dehydrated media and dispense aseptically into sterile Petri-dishes. Media in Petri-dishes are ready to use.

FORMULA in g/l

Peptones	16,50
Lactose	10,00
Sucrose	1,00
Glucose	0,50
Acid fuchsin	0,08
Agar	15,00

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: 48 h
Salmonella typhi ATCC 19430		Good, colourless colonies	
Escherichia coli ATCC 25922		Slightly inhibited, red colonies	
Proteus mirabilis ATCC 29906		Partially inhibited, colourless colonies without swarming	
Enterococcus faecalis ATCC 29212		Inhibited	

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): **Brilliant Green Agar Base, Human**
Product name (bottled media): **Brilliant Green Agar Base, Human**
Product name (ready to use media): **Brilliant Green Agar, Human**
Code number: **BGH**
Supplement (in ready to use media) **Brilliant Green Solution, Sterile (BGS)**
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.

Harmful components according to Regulation (EU) No. 1272/2008

Component (supplement)	Classification	Concentration (in ready to use media)
Brilliant Green		
CAS-No.: 633-03-4 EU-No.: 211-190-1	Acute Tox. Oral 4; Eye Irrit. 2; H302, H319; P305+351+338	< 1 %

Full text of the H and P phrases: see in section 16.

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.

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):	Beige
Odor (dehydrated medium):	No information available
pH before autoclaving (25 °C):	7,3 approx.
Appearance (ready to use medium):	Gel
Colour (bottled medium):	Pink
Colour (plated medium):	Bluish
Odor (ready to use medium):	No information available
pH (ready to use medium, 25 °C):	7,2 – 7,4
Water solubility:	> 43 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.

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.

16. OTHER INFORMATION
Full text of H and P phrases:

H302	Harmful if swallowed.
H319	Causes serious eye irritation.

P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

The changed section(s) of Safety Data Sheet: 1.1; 3.2; 16

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.

Certificate of analysis

Name:	**BRILLIANT GREEN AGAR BASE, HUMAN**
	for diagnostics purpose
Code Number:	BGH20500
Lot:	BGH120917062
Manufacture Date:	09/2017
Expiry Date:	09/2020

Dehydrated Media:

Colour:	Pinkish
Appearance:	Homogeneous hygroscopic powder

Prepared Medium:

Directions:	**43 g/l**
Clarity:	Transparent
Deposit:	None
Gel strength	Correct
pH before autoclaving:	7,2 - at 20 °C
Sterilization:	By autoclaving at 121 °C for 15 minutes
Remarks:	Supplement: Brilliant Green Solution, 0,1% (BGS800010-DC)

Microbiological assay:

Incubation temperature:	37 °C
Incubation time:	24 h

Quality control

Test strains	**Growth**
Escherichia coli	Partial inhibition, red colonies
Salmonella typhi	Good, colourless colonies
Proteus mirabilis	Partial inhibition, colourless colonies without swarming
Enterococcus faecalis	Inhibition

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.

Hereby we declare:

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 oh 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.

This certificate was issued electronically and is valid without signature.