SAFETY DATA SHEET

according to Regulation (EC) No. 2015/830

1. IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

1.1 Product identifiers

BIOLAB Antimicrobial Susceptibility Testing DiscCode number:SPProduct name:Spiramycin

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

Recommended use:Microbiological diagnostics, IVD productUses 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:	<u>export@biolab.hu</u>

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

No hazardous product as specified in Directive 67/548/EEC.

Hazard overview: This product is not classified as hazardous. This product is for laboratory use only and should not be taken internally. People who are known to have suspected allergies to antibiotics can be irritated if disc contact with skin.

Hazard Rating:

Health – 0 Fire – 0 Reactivity – 0

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	
Chemical characteriazation:	This product consists of a mixture with the generic listed below and some other substances with no hazardous additions.
Ingredient name:	Spiramycin
CAS Number:	8025-81-8
EC Number:	232-429-6
<u>3.2 Mixtures</u>	
It is not necessary to publish the components.	

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4. FIRST AID MEASURES		
After inhalation:	Obtain medical treatment in any case of problem.	
After skin contact:	Wash with soap and water. In case of irritation consult a	
	physician.	
After eyes contact:	Wash with soap and water. In case of irritation consult	
	physician.	
After ingestion:	Wash out mouth with plenty of water and consult a physician.	
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5. FIRE FIGHTING MEASURES		
	Water anne annexista form on hon disvide or dry showing	
Suitable Extinguishing Media:	Water spray, appropriate foam carbon dioxide or dry chemical	
Ducto stine Escuiron ent	powder.	
Protective Equipment:	In case of any need use only approved respirator or equivalent.	
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6. ACCIDENTAL RELEASE MEA		
Person-related precautionary m	neasures: Do not handle directly; use disposable gloves to pick	
	up.	
Procedures of cleaning:	No special instrument needed. Sweep into suitable containers	
	and dispose with normal laboratory trash.	
7. HANDLING AND STORAGE		
Handling:	Do not handle discs directly. Use a disc dispenser or forceps. Do	
0	not breathe dust. Avoid contact with eyes, skin and clothing.	
	Since the products have been stored together with silica gel as	
	a desiccant, they may cause irritation.	
Storage:	Store at -20 to $+8^{\circ}$ C in refrigerator or freezer and keep in the	
	sealed containers provided.	
	r	
8. EXPOSURE CONTROLS/PER	SONAL PROTECTION	
Ventilation:	Not required under normal laboratory conditions.	
	Respirator is not required under normal laboratory conditions.	
reisonal protection equipment.	Personal allergic to generic powder should wear an approved	
Pody protoction.	mask or use the discs in a well-ventilated atmosphere. Lab coats	
Body protection: Eye protection:	Safety glasses are not required under normal laboratory	
Eye protection:		
Hand protoction	conditions.	
Hand protection	Use disposable chemical resistant gloves and wash hands at	
	working with this medium.	
9. PHYSICAL AND CHEMICAL P		
Physical State:	Paper discs printed with code, impregnated with antimicrobial	
	or chemical reagents/substrates. Discs are contained in a	
	plastic cartridge tube and packed in sealed foil bags with	
	desiccant. Each cartridge contains 50 discs.	
Colour:	Generally white but may vary.	

	Generally white but may vary.	
Odor:	Odorless	
Solubility in water:	Insoluble	
pH:	Range 4 to 8	

10. STABILITY AND REACTIVI	ГҮ
Stability:	Stable

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Materials to be avoided:	No dangerous reactions known	
Stability conditions to avoid:	: Temperatures over +8°C or below -20°C	
Hazardous decomposition produc	ct: No dangerous decomposition products known	

11. TOXICOLOGICAL INFORMATIONS		
Acute Toxicity:	Low	
After skin contact:	Probability of allergic sensitization	
After eye contact:	Dust with generic powder and/or silica gel may irritate eyes.	
After ingestion:	Ingestion of large amounts may cause nausea, vomiting,	
	headaches and dizziness.	
After inhalation:	Dust with generic powder and/or silica gel may irritate	
	respiratory tract.	

12. ECOLOGICAL INFORMATIONS		
Ecotoxicity:	Not determined	
General information:	Not hazardous for water	

13. DISPOSAL CONSIDERATION			
Waste disposal:	May be disposed off with normal laboratory trash in		
	accordance with applicable state regulations.		
Container information:	Containers should be cleaned by proper technique and then can be reused or disposed		

UN / NA Number:	Not classified
DOT Classification:	Not a DOT controlled material (US)
ADR/RID Classification:	Not controlled under ADR (Europe)

15. REGULATORY INFORMA	TION	
Labelling according to EC Dire	ectives	
Warning Label Text:		
Indication of Hazard:	None	
Risk Statements:	None	
Safety Statements:	None	
Carcinogenicity:		
IARC:	No	
OSHA:	No (US)	

16. OTHER INFORMATION

Full text of H and P phrases: -

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.

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