

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 Disc

Code number: AK

Product name: Amikacin

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

Recommended use: Microbiological diagnostics, IVD product

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

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 characterization: This product consists of a mixture with the generic listed below and some other substances with no hazardous additions.

Ingredient name: Amikacin

CAS Number: 364622-82-2

EC Number: 200-394-6

3.2 Mixtures

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 a physician.
After ingestion:	Wash out mouth with plenty of water and consult a physician.

5. FIRE FIGHTING MEASURES

Suitable Extinguishing Media:	Water spray, appropriate foam carbon dioxide or dry chemical powder.
Protective Equipment:	In case of any need use only approved respirator or equivalent.

6. ACCIDENTAL RELEASE MEASURES

Person-related precautionary measures:	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 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°C in refrigerator or freezer and keep in the sealed containers provided.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ventilation:	Not required under normal laboratory conditions.
Personal protection equipment:	Respirator is not required under normal laboratory conditions. Personal allergic to generic powder should wear an approved mask or use the discs in a well-ventilated atmosphere.
Body protection:	Lab coats
Eye protection:	Safety glasses are not required under normal laboratory conditions.
Hand protection	Use disposable chemical resistant gloves and wash hands after working with this medium.

9. PHYSICAL AND CHEMICAL PROPERTIES

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.
Odor:	Odorless
Solubility in water:	Insoluble
pH:	Range 4 to 8

10. STABILITY AND REACTIVITY

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 product:	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

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

Labelling according to EC Directives

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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