

# SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 23-Feb-2022 Revision Number 1

# SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name Amikacine 30 μg - AST Disks, 4x50 Disks

**Catalogue Number(s)** 66148, 3566148\*\*\*

Pure substance/mixture Mixture

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

Recommended use Restricted to professional users

In vitro diagnostic

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

 Corporate Headquarters
 Manufacturer

 Bio-Rad Laboratories Inc.
 Bio-Rad

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Hercules, CA 94547 92430 Marnes-la-Coquette

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Bio-Rad Laboratories Pvt. Ltd.

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South Africa: cdg\_techsupport\_eemea@bio-rad.com

1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Ireland: 353-19014670

CHEMTREC India: 000-800-100-7141 CHEMTREC South Africa: 0-800-983-611

# **SECTION 2: Hazards identification**

#### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

### 2.2. Label elements

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This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

**Hazard statements** 

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

#### 2.3. Other hazards

# **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Not applicable

3.2 Mixtures

### Full text of H- and EUH-phrases: see section 16

#### **Acute Toxicity Estimate**

No information available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

### **SECTION 4: First aid measures**

### 4.1. Description of first aid measures

Inhalation Remove to fresh air.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a doctor.

Skin contact In the case of skin irritation or allergic reactions see a doctor. Wash skin with soap and

Rinse mouth. Ingestion

#### 4.2. Most important symptoms and effects, both acute and delayed

**Symptoms** No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically. Note to doctors

# **SECTION 5: Firefighting measures**

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Use extinguishing measures that are appropriate to local circumstances and the

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

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Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

### **SECTION 6: Accidental release measures**

6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Ensure adequate ventilation.

6.2. Environmental precautions

**Environmental precautions** See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

# **SECTION 7: Handling and storage**

7.1. Precautions for safe handling

Advice on safe handling Ensure adequate ventilation.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store according to product and label instructions.\*\*\*

7.3. Specific end use(s)

**Risk Management Methods (RMM)** The information required is contained in this Safety Data Sheet.

### **SECTION 8: Exposure controls/personal protection**

8.1. Control parameters

**Exposure Limits** This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

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### **Biological occupational exposure limits**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

**Derived No Effect Level (DNEL)** Predicted No Effect Concentration No information available.

No information available.

(PNEC)

8.2. Exposure controls

Personal protective equipment

Eye/face protection No special protective equipment required.

No special protective equipment required. Skin and body protection

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

No information available. **Environmental exposure controls** 

# SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Solid **Appearance** solid Colour black Odour Odourless.

**Odour threshold** No information available

Remarks • Method Values **Property** 

No data available Melting point / freezing point None known Boiling point / boiling range No data available None known Flammability (solid, gas) No data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Flash point No data available None known None known **Autoignition temperature** No data available **Decomposition temperature** None known

None known pН

pH (as aqueous solution) No data available No information available Kinematic viscosity No data available None known **Dynamic viscosity** No data available None known

Water solubility Insoluble in water

Solubility(ies) No data available None known No data available **Partition coefficient** None known No data available Vapour pressure None known None known

Relative density No data available

**Bulk density** No data available **Liquid Density** No data available

No data available None known Vapour density

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Particle characteristics

**Particle Size** No information available **Particle Size Distribution** No information available

9.2. Other information

9.2.1. Information with regards to physical hazard classes

Not applicable

9.2.2. Other safety characteristics

No information available

# **SECTION 10: Stability and reactivity**

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

**Explosion data** 

Sensitivity to mechanical impact None. Sensitivity to static discharge

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

# **SECTION 11: Toxicological information**

# 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

**Product Information** 

Inhalation Specific test data for the substance or mixture is not available.

Specific test data for the substance or mixture is not available. Eye contact

Skin contact Specific test data for the substance or mixture is not available.

Specific test data for the substance or mixture is not available. Ingestion

Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** No information available.

Acute toxicity

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### **Numerical measures of toxicity**

Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Skin corrosion/irritation**No information available.

Serious eye damage/eye irritation No information available.

**Respiratory or skin sensitisation** No information available.

Germ cell mutagenicity No information available.

**Carcinogenicity** No information available.

Reproductive toxicity No information available.

**STOT - single exposure**No information available.

**STOT - repeated exposure**No information available.

**Aspiration hazard** No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

11.2.2. Other information

Other adverse effects No information available.

**SECTION 12: Ecological information** 

12.1. Toxicity

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

**Unknown aquatic toxicity**Contains 0 % of components with unknown hazards to the aquatic environment.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

**Bioaccumulation** There is no data for this product.

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12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

12.7. Other adverse effects

No information available.

### **SECTION 13: Disposal considerations**

13.1. Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

# **SECTION 14: Transport information**

#### <u>IATA</u>

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

### IMDG

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions Non

14.7 Maritime transport in bulk

No information available

according to IMO instruments

#### RID

14.1 UN numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

<u>ADR</u>

14.1 UN number or ID number
14.2 UN proper shipping name
14.3 Transport hazard class(es)

Not regulated
Not regulated
Not regulated

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14.4 Packing group Not regulated 14.5 Environmental hazards Not applicable

14.6 Special Precautions for Users

**Special Provisions** None

# **SECTION 15: Regulatory information**

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

### National regulations

Germany

Water hazard class (WGK) non-hazardous to water (nwg)

### **European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

### **Persistent Organic Pollutants**

Not applicable

### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

**International Inventories** Contact supplier for inventory compliance status

15.2. Chemical safety assessment

**Chemical Safety Report** No information available

### **SECTION 16: Other information**

### Key or legend to abbreviations and acronyms used in the safety data sheet

Legend

SVHC: Substances of Very High Concern for Authorisation:

### Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA (time-weighted average) STEL (Short Term Exposure Limit) TWA STEL

Maximum limit value Ceiling Skin designation

Classification procedure		
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used	
Acute oral toxicity	Calculation method	
Acute dermal toxicity	Calculation method	
Acute inhalation toxicity - gas	Calculation method	

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Acute inhalation toxicity - vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

#### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA\_RAC)

European Chemicals Agency (ECHA) (ECHA\_API)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

National Institute of Technology and Evaluation (NITE)

Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications

Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme

Organisation for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision Note Significant changes throughout SDS. Review all sections

Revision date 23-Feb-2022

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet** 

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