

Date Prepared: 03/24/2014

Reviewed On: 03/24/2014

1 Identification

- · Product Identifier
- · Product Name: Amikacin AN-30
- · Catalog Number: 231597
- Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture In-vitro Diagnostics
- · Details of the supplier of the safety data sheet
- Manufacturer/Supplier: BD Diagnostic Systems
 7 Loveton Circle
 Sparks, MD 21152
 Telephone: (410) 771 - 0100 or (800) 638 – 8663
 Email Address: Technical_Services@bd.com
 Information Department: Technical Service
- Emergency telephone number: In case of a chemical emergency, spill, fire, exposure, or accident, contact BD Diagnostic Systems (410) 771-0100 or (800)-638-8663, or ChemTrec at (800) 424-9300.

2 Hazard(s) identification

• Classification of the substance or mixture The product is not classified according to the Globally Harmonized System (GHS).

· Classification according to Directive 67/548/EEC or Directive 1999/45/EC

This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200, the Canada's Workplace Hazardous Materials Information System (WHMIS) and the European Directive 67/548/EEC and 1999/45/EC.

· Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· Label elements

- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · NFPA ratings (scale 0-4)



Health = 0 Flammability = 0 Reactivity = 0

· HMIS ratings (scale 0-4)



(Contd. on page 2)



Date Prepared: 03/24/2014

Reviewed On: 03/24/2014

Product Name: Amikacin AN-30

(Contd. of page 1)

- · Other hazards
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Mixture
- · **Description:** Mixture consisting of the following components.
- · Dangerous Components: Void
- · Additional information Risk phrases refer to section 15.

4 First-aid measures

- Description of first aid measures
- · General information No special measures required.
- · After inhalation Seek medical treatment in case of complaints.
- · After skin contact Immediately wash with water and soap and rinse thoroughly.
- After eye contact Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
 - · After swallowing If symptoms persist consult doctor.
 - · Information for doctor Show this product label or this MSDS.
 - *Most important symptoms and effects, both acute and delayed* No further relevant information available.
 - Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- Suitable extinguishing agents CO2, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.
- Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures Not required.

• Environmental precautions: Wipe up with damp sponge or mop.

(Contd. on page 3)

US



Date Prepared: 03/24/2014

Reviewed On: 03/24/2014

Product Name: Amikacin AN-30

(Contd. of page 2)

Methods and material for containment and cleaning up: No special measures required.
 Reference to other sections No dangerous substances are released.

7 Handling and storage

- · Handling
- · Precautions for safe handling No special measures required.
- Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage
- · Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Store away from oxidizing agents.
- · Further information about storage conditions: None.
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- Additional information about design of technical systems: No further data; see Section 7.
- · Control parameters
- **Components with limit values that require monitoring at the workplace:** The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- · Personal Protective Equipment
- · General protective and hygienic measures
- The usual precautionary measures for handling chemicals should be followed.
- · Breathing equipment: Not required.
- · Protection of hands:



Chemical resistant gloves (i.e. nitrile, or equivalent).

- · Eye protection: Safety glasses
- · Body protection: Protective work clothing (lab coat).

(Contd. on page 4)



Date Prepared: 03/24/2014

Reviewed On: 03/24/2014

Product Name: Amikacin AN-30

(Contd. of page 3)

| Information on basic physica General Information | al and chemical properties |
|---|---|
| Appearance: | |
| Form: | Solid. |
| Color: | According to product specification |
| Odor: | Characteristic |
| Change in condition | Undetermined |
| Melting point/Melting range: | Not determined |
| Boiling point/Boiling range: | Not determined |
| Flash point: | Not applicable |
| Flammability (solid, gaseous |) Product is not flammable. |
| Danger of explosion: | Product does not present an explosion hazard. |
| Density: | Not determined |
| Solubility in / Miscibility with | |
| Water: | Insoluble |
| Solvent content: | |
| Solids content: | 100.0 % |
| • Other information | No further relevant information available. |

10 Stability and reactivity

- · Reactivity
- · Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · Primary irritant effect:
- · on the skin: No irritating effect.
- on the eye: No irritating effect.
- · Sensitization: Sensitizing effect through inhalation is possible with prolonged exposure.

(Contd. on page 5)

US -



Date Prepared: 03/24/2014

Reviewed On: 03/24/2014

Product Name: Amikacin AN-30

(Contd. of page 4)

· Additional toxicological information:

The product is not subject to OSHA classification according to internally approved calculation methods for preparations.

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

· NTP (National Toxicology Program)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Ecotoxical effects:
- · Other information:

The ecological effects have not been thoroughly investigated, but currently none have been identified.

- · Additional ecological information:
- · General notes: Generally not hazardous for water.
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Smaller quantities can be disposed of with solid waste.

Dispose of material in accordance with federal (40 CFR 261.3), state and local requirements. This product is not considered a RCRA hazardous waste.

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to state and federal regulations.
- · Recommended cleansing agent: Water, if necessary with cleansing agents.

(Contd. on page 6)

us



Date Prepared: 03/24/2014

Reviewed On: 03/24/2014

Product Name: Amikacin AN-30

(Contd. of page 5)

| · UN-Number | |
|---|---|
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Void |
| Environmental hazards: Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| Transport in bulk according to Annex MARPOL73/78 and the IBC Code | ll of Not applicable. |
| · Transport/Additional information: | If a "void" appears in the Hazard Class sectio for the type of transportation, this indicates th product is not regulated for transportation. |
| · UN "Model Regulation": | - |

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- · SARA Section 355 (extremely hazardous substances)
- None of the ingredients is listed.
- · SARA Section 313 (specific toxic chemical listings)

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act)

39831-55-5 amikacin

· California Proposition 65 - Chemicals known to cause cancer

None of the ingredients is listed.

 California Proposition 65 - Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

(Contd. on page 7)

US



Date Prepared: 03/24/2014

Reviewed On: 03/24/2014

Product Name: Amikacin AN-30

(Contd. of page 6)

- · California Proposition 65 Chemicals known to cause reproductive toxicity for males:
- None of the ingredients is listed.
- California Proposition 65 Chemicals known to cause developmental toxicity:

39831-55-5 amikacin

· Carcinogenic categories

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- Hazard statements Void
- · National regulations
- · Water hazard class: Generally not hazardous for water.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

- Department issuing MSDS: Environmental, Health & Safety
- Created by Michael J. Spinazzola
- · Contact: Technical Service Representative
- · Date of preparation / last revision 03/24/2014 / -
- · Abbreviations and acronvms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail) IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA) ICAO: International Civil Aviation Organization ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO) ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods DOT: US Department of Transportation IATA: International Air Transport Association ACGIH: American Conference of Governmental Industrial Hygienists EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA)