



300 Northfield Road
 Bedford, OH 44146
 Telephone: (440) 232-3320
 -or- (800) 562-4797

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Doxycycline for Injection, USP
Chemical Names: 2-Naphthacenecarboxamide,4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-
Synonyms: Vibramycin Intravenous, Doxycycline, Liviatin, Doxyciclina, GS-3056
Manufacturer's Name: BEN VENUE LABORATORIES, INC.
Address: 300 NORTHFIELD ROAD
 BEDFORD, OH 44146
Emergency Telephone Number: Chemtrec: 1(800)424-9300
Telephone Number for Info.: (440)232-3320 -or- (800)562-4797
Medical Emergency: Professional Services 1(800)521-5169
Date Prepared: October 22, 2001

Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Doxycycline Hyclate	17.24	564-25-0	NONE	NONE	NONE
Ascorbic Acid	82.76	50-81-7	NONE	NONE	NONE

Doxycycline is a sterile lyophilized drug provided in a vial.

Section III - HEALTH HAZARD DATA

Routes of Entry: Under normal use, Doxycycline presents little hazard. It may be absorbed through the skin, through ingestion or via inhalation of aerosols.
Health Hazard (Acute & Chronic): Doxycycline is a broad spectrum antibiotic used to treat a variety of gram positive and gram negative organisms. It may affect the digestive system and may cause allergic reactions.
Carcinogenicity: NTP? NO IARC Monographs? NONE
 OSHA Regulated? NO
Signs & Symptoms of Exposure: Doxycycline may cause irritation to the eyes, skin and respiratory tract. It may also cause nausea, vomiting diarrhea, and difficulty in swallowing. May cause allergic reaction.
Medical Conditions Generally Aggravated by Exposure: Persons who are allergic to tetracyclines.
BVL Hazard Category: 2

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 or more minutes.

Skin Exposure: Wash skin with cool, soapy water for 15 minutes.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.

Inhalation: If difficulty breathing, administer oxygen. Seek attention of a physician immediately. If necessary, provide artificial respiration.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not Applicable **LEL:** Not Applicable **UEL:** Not Applicable

Flammable Limits: Not Applicable

Extinguishing Media: Use water or an ABC multi-purpose extinguisher.

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke.

Unusual Fire/Explosion Hazards: NONE

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Wet and wipe up Doxycycline with absorbent materials and dispose according to local, state, and federal guidelines.

Release to Air: If aerosolized, reduce exposures by ventilating area; clean up spill immediately to prevent dusting.

Release to Water: Refer to local water authority. Drain disposal is not recommended; however, refer to local, state, and federal disposal guidelines.

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above.

Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

Waste Disposal Method: Incineration in an approved incinerator is recommended. Refer to local, state, and federal rules.

Precautions to be taken in handling and storing: Store at 25° C (77°F). Follow instructions provided in packaging. Protect from light.

Other Precautions: NONE

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

Ventilation: Handle product in a well-ventilated area.

Protective Gloves: Latex or nitrile

Eye Protection: Safety glasses
Other Protective Clothing or Equipment: Lab Coat

Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking while handling this product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Solid	Specific Gravity: Not Applicable
Appearance and Odor: White, odorless	Melting Point: Unknown
Boiling Point: Not Applicable	Evaporation Rate: Not Applicable
Vapor Pressure: Not Applicable	Solubility in Water: Soluble
Vapor Density: Not Applicable	pH: 6.0-7.5

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable

Incompatibility (Materials to Avoid): Strong oxidizers or water-reactive materials.

Hazardous Decomposition or Byproducts: Decomposition products of this compound may include potentially hazardous byproducts of nitrogen oxides, carbon monoxide, carbon dioxide, and sulfur oxides.

Hazardous Polymerization: Will not occur

Conditions to Avoid: Storage near oxidizers and water reactive materials

Section XI - TOXICOLOGICAL INFORMATION

For Doxycycline

LD₅₀ mouse, intravenous = 241 mg/kg

LD₅₀ mouse, oral = 1870 mg/kg

LD₅₀ rat, intraperitoneal = 378 mg/kg

LD₅₀ rat, intravenous = 228 mg/kg

LD₅₀ rat, oral = >2 g/kg

LD₅₀ mouse, intraperitoneal = 410 mg/kg

LD₅₀ dog, intravenous = >100 mg/kg

LD₅₀ dog, oral = >500 mg/kg

Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Doxycycline. Handle in a manner to prevent spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dispose of by incineration at an approved/permitted incinerator.
Review local, state, and federal regulations for your regulatory area.

Section XIV - TRANSPORTATION INFORMATION

Doxycycline is not a DOT hazardous material.

Doxycycline is not a DOT Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO

CERCLA listed?: NO

RCRA listed?: NO

Doxycycline is listed on California's Proposition 65 List as Code D

Section XVI - OTHER DATA

1. Use of this product should be through or under the direction of a physician.
This MSDS does not address therapeutic use of this material.
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.

The information provided is believed to be complete and accurate. It is the user's responsibility to use the information according to their application. Bedford Laboratories and Ben Venue Labs, Inc. assumes no additional liability or responsibility resulting from the use of or reliance on this information.