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Section 1 - Identification


- (a) **Product Identifier:** Doxycycline for Injection, USP
- (b) **Product Code:** 83634-111
- Common/Trade Name:** Vibramycin
- Chemical Name:** alpha-6-deoxy-5-oxytetracycline
- Chemical Family:** Antibacterial Agent
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Avenacy 10 N. Martingale Road, Suite 225, Schaumburg, IL 60173, 847-773-4901
- (e) **Emergency Telephone:** 855-283-6229

Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:** Acute toxicity, Oral (Category 4)
Skin irritation (Category 2)
Eye irritation (Category 2)
Reproductive toxicity (Category 2)
Specific target organ toxicity - single exposure (Category 3)
Respiratory system (Category 1)
Long-term (chronic) aquatic hazard (Category 3)

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):

GHS Signal Word:	Warning
GHS Hazard Statement:	H302 - Harmful if swallowed. H315 - Causes skin irritation. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation. H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child. H412 - Harmful to aquatic life with long lasting effects.
GHS Symbols:	 

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GHS Precautionary Statements:	<p>P202 - Do not handle until all safety precautions have been read and understood.</p> <p>P273 - Avoid release to the environment.</p> <p>P301 + P312 - IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.</p> <p>P302 + P352 - IF ON SKIN: Wash with plenty of water.</p> <p>P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P308 + P313 - IF exposed or concerned: Get medical advice/ attention.</p>
Other Hazards	No additional information available.


(d) Unknown Acute Toxicity N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
alpha-6-deoxy-5-oxytetracycline	Doxycycline Hyclate	100 mg/vial	24390-14-5	N/A
Ascorbic Acid	Ascorbic Acid	480 mg/vial	50-81-7	N/A
Mannitol	Mannitol	300 mg/vial	69-65-8	N/A

Section 4 – First Aid Measures

Eye Exposure:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Exposure:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Injection:	See patient package insert in shipping carton for complete information.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

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Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray
- (b) **Hazardous Combustion Products:** Carbon oxides, Nitrogen oxides (NO_x), Hydrogen chloride gas. Development of hazardous combustion gases or vapors possible in the event of fire.
- (c) **Special Protective Equipment / Precautions:** Wear approved, positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

Section 6 - Accidental Release Measures

- Spill:** Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing dust. Use proper personal protective equipment as listed in section 8.
- Environmental Precautions:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.


Section 7 - Handling and Storage

- General Handling:** Minimize dust generation and accumulation. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases.
- Storage Conditions:** Store as directed by product packaging.

Section 8 - Exposure Controls / Personal Protection

(a) Engineering Controls

General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.


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(b) Individual Protection Measures

Respiratory Protection:	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-17a or international equivalent.)
Eye Protection:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin Protection:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Other Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Additional Exposure Precautions:	None available.

Section 9 - Physical and Chemical Properties

(a)	Appearance	Yellow powder
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	Not available
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available

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(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Soluble in water
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity


(a)	Reactivity	No data available.
(b)	Chemical Stability	The product is stable under normal conditions of use.
(c)	Possibility of Hazardous Reactions	None known.
(d)	Conditions to Avoid	Fine particles (such as dust and mists) may fuel fires/explosions.
(e)	Incompatible Materials	Keep away from strong oxidizers.
(f)	Hazardous Decomposition Products	Carbon oxides, Nitrogen oxides (NO _x), Hydrogen chloride gas. Development of hazardous combustion gases or vapors possible in the event of fire.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Skin, eyes, inhalation, ingestion.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	See product package insert for full details
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	See product package insert for full details

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Doxycycline	LD ₅₀	IV	Mouse	241 mg/kg
Doxycycline	LD ₅₀	IP	Mouse	410 mg/kg

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Doxycycline	LD ₅₀	IV	Rat	228 mg/kg
Doxycycline	LD ₅₀	IP	Rat	228 mg/kg
Doxycycline	LD ₅₀	IV	Dog	>100 mg/kg
Doxycycline	LD ₅₀	Oral	Mouse	1870 mg/kg
Doxycycline	LD ₅₀	Oral	Rat	>2 g/kg
Doxycycline	LD ₅₀	Oral	Dog	>500 mg/kg

(e) Hazardous Chemical Listings

NTP: Not Listed IARC: Not Listed OSHA: Not Listed

Section 12 - Ecological Information

(a)	Ecotoxicity	No data available.
(b)	Persistence and degradability	No data available.
(c)	Bioaccumulative potential	No data available.
(d)	Mobility in soil	No data available
(e)	Other Adverse	No data available


Section 13 - Disposal Considerations

Waste Disposal: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and waste water.

Section 14 - Transport Information

DOT: Not regulated as a dangerous good.
IATA: Not regulated as a dangerous good.
IMDG: Not regulated as a dangerous good.

(a)	UN Number	N/A
(b)	UN Proper Shipping Name	N/A
(c)	Transport Hazard Class(es)	N/A

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(d)	Packing Group	N/A
(e)	Environmental Hazards	N/A
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g)	Special Precautions	N/A

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Avenacy usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA – Not listed

CERCLA - Not on this list

SARA 302/304 - Not on this list

SARA 313 - Not on this list

Section 16 - Other Information


As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Avenacy
10 N. Martingale Road, Suite 225
Schaumburg, IL 60173
847-773-4901

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice

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CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System