SAFETY DATA SHEET

Doxycycline Injection, USP

1) PRODUCT AND COMPANY IDENTIFICATION

Product Identifier:	Doxycycline Injection
Common/Trade Name:	Doxy 100
Chemical Name:	N/A
Chemical Family:	Mixture
Product Use:	Antibiotic Agent
Product Type:	Regulated Prescription Drug
Manufacturer:	Piramal Critical Care, Inc 268 Brodhead Road Bethlehem, PA, 18017
Important Phone Numbers:	Customer Service: 610-974-9760 x 510 E-Mail: pcccustomerconnect@piramal.com CHEMTREC 1-800-424-9300 (For Transportation in US and Canada)

2) HAZARDS IDENTIFICATION

GHS Pictograms



Signal Word: DANGER.

GHS Class:

Respiratory sensitisation. Category 1.
Reproductive toxicity. Category 1A.
Eye Irritation. Category 2.
Skin Irritation. Category 2.
Skin Sensitization. Category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May damage fertility or the unborn child.
Causes serious eye irritation.
Causes skin irritation.
May cause an allergic skin reaction.
May cause harm to breast-fed children.

Precautionary Statements: Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid contact during pregnancy and while nursing.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see ... on this label).
If skin irritation occurs: Get medical advice/attention.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Take off contaminated clothing and wash it before reuse.
Store locked up.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

Eye: Contact with eyes may cause irritation.

Skin: May cause skin irritation.

Inhalation: May cause irritation of respiratory tract.

Ingestion: May cause irritation.

Signs/Symptoms: Possible adverse reactions include: anorexia, nausea, vomiting, diarrhea, glossitis, dysphagia, enterocolitis, inflammatory lesions (in the anogenital region), maculopapular and erythematous rashes, exfoliative dermatitis, urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, pericarditis, hemolytic anemia, thrombocytopenia, neutropenia, and eosinophilia. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Accidental Exposure: Hypersensitivity to any of the tetracyclines.

3) COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent
Doxycycline	24390-14-5	100 mg vial
Ascorbic Acid	50-81-7	480 mg per vial
Mannitol	69-65-8	300 mg per vial

4) FIRST AID MEASURES

Eye Contact: 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 Contact: 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.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

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.

5) FIRE FIGHTING MEASURES

Flash Point: Not established.

Flash Point Method: Not established.

Auto Ignition Temperature: Not established.

Lower Flammable/Explosive Limit: Not established.

Upper Flammable/Explosive Limit: Not established.

Fire Fighting Instructions: Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.

Extinguishing Media: Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Protective Equipment: As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

Hazardous Combustion Byproducts: Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

6) ACCIDENTAL RELEASE MEASURES

Personnel Precautions:	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:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	This material will settle out of the air.
Methods for cleanup:	Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

7) HANDLING AND STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 15 to 30°C (59 to 86°F). Protect from light.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling dust, vapor or mist.

8) EXPOSURE CONTROLS/PERSONAL PROTECTION

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.

Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

9) PHYSICAL AND CHEMICAL PROPERTIES

Color	Yellow
Physical state	Lyophilized powder
Odor	Slight
Percent Volatile	Not established
pH	1.8-3.3
Melting Point:	Not established
Boiling Point:	Not established
Flash Point	Not established
Flash Point Method	Not established
Molecular Formula	Mixture
Molecular Weight	1025.89
Vapor Pressure:	Not established
Vapor Density:	Not established
Relative Density	Not available
Solubility(ies)	Soluble in water
Partition Coefficient: n-octanol/water	Not established
Auto-ignition Temperature	Not established
Decomposition Temperature	Not established
Viscosity	N/A

10) STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Exposure to light and excessive heat above 30 °C may cause decomposition.

11) TOXICOLOGICAL INFORMATION

Doxycycline :

Acute Toxicity:
LD50 IV Mouse: 241 mg/kg
LD50 IP Mouse: 410 mg/kg
LD50 IV Rat: 228 mg/kg
LD50 IP Rat: 228 mg/kg
LD50 IV Dog: > 100 mg/kg

Skin: IMMEDIATE EFFECTS: Skin irritation may occur.

Chronic Effects: Hypersensitivity reactions ranging from mild to severe may occur.

Doxycycline :

Ingestion:
LD50 Oral Mouse: 1870 mg/kg
LD50 Oral Rat: > 2 gm/kg
LD50 Oral Dog: > 500 mg/kg

Other Toxicological Information:
LD50 IV Mouse: 241 mg/kg
LD50 IP Mouse: 410 mg/kg
LD50 IV Rat: 228 mg/kg
LD50 IP Rat: 228 mg/kg LD50 IV Dog: > 100 mg/kg

Ascorbic Acid :
RTECS Number: CI7650000
Skin: Administration onto the skin - Mouse TDLo: 50 mg/kg [Immunological Including Allergic - Increase in cellular immune response]
Administration onto the skin - Mouse TDLo: 500 mg/kg/10D (Intermittent) [Biochemical - Metabolism (Intermediary) - Effect on inflammation or mediation of inflammation]
Administration onto the skin - Mouse TDLo: 120 gm/kg/30D (Intermittent) [Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - Other oxidoreductases]

Ingestion:	**Oral - Rat LD50: 11900 mg/kg [Sense Organs and Special Senses (Eye) - Lacrimation Behavioral - Somnolence (general depressed activity) Gastrointestinal -**

Hypermotility, diarrhea]
Oral - Mouse LD50: 3367 mg/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Rat LD50: 11.9 gm/kg [Behavioral - Muscle contraction or spasticity Lungs, Thorax, or
Respiration - Dyspnea Nutritional and Gross Metabolic - Body temperature decrease]

Other Toxicological Information:

Intravenous. - Rat LD50: >4 gm/kg [Behavioral - altered sleep time (including change in righting reflex) Behavioral - somnolence (general depressed activity)]
Intravenous. - Mouse LD50: 518 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Mouse TDLo: 800 mg/kg [Reproductive - Specific Developmental Abnormalities - Central
Nervous System Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Subcutaneous - Rat LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 643 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse TDLo: 90 mg/kg [Behavioral - rigidity (including catalepsy)]
Intraperitoneal. - Mouse Micronucleus test: 4500 mg/kg/3D (continuous)
Intraperitoneal. - Mouse Cytogenetic analysis: 1600 mg/kg
Intraperitoneal. - Mouse Sister chromatid exchange: 1600 mg/kg
Intraperitoneal. - Mouse TDLo: 6680 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death]

Mannitol :

RTECS Number: **OP2060000**

Ingestion:

Oral - Rat LD50: 13500 mg/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Mouse LD50: 22 gm/kg [Behavioral - Somnolence (general depressed activity); Gastrointestinal
- Ulceration or bleeding from small intestine]

Other Toxicological Information:

Intravenous. - Rat LD50: 9690 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Mouse LD50: 7470 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 14 gm/kg [Details of toxic effects not reported other than lethal dose value]

12) ECOLOGICAL INFORMATION

Ecotoxicity:	**No ecotoxicity data was found for the product.**
Environmental Stability:	**No environmental information found for this product.**

13) DISPOSAL CONSIDERATIONS

Waste Disposal:Dispose of in accordance with Local, State, Federal and Provincial regulations.

14) TRANSPORT INFORMATION

DOT Shipping Name:	**Not Regulated.**
DOT UN Number:	**Not Regulated.**
IATA Shipping Name:	**Not Regulated**

15) REGULATORY INFORMATION

Doxycycline :

California PROP 65:	**Listed: developmental.**
Canada DSL:	**Listed**

Ascorbic Acid :

TSCA Inventory Status:	**Listed**
EINECS Number:	**200-066-2**
Canada DSL:	**Listed**

Mannitol :

TSCA Inventory Status:	**Listed**
EINECS Number:	**200-711-8**
Canada DSL:	**Listed**

16) OTHER INFORMATION

HMIS Ratings:

HMIS Health 1
Hazard:
HMIS Fire Hazard: 1
HMIS Reactivity: 1
HMIS Reactivity: 1
HMIS Personal Protection: X

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SDS Updates:
10-04-2021 – New Document
06-16-2023 – Added IATA reference in Section 14