

DENTSPLY Tulsa Dental Specialties

Safety Data Sheet

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1. PRODUCT IDENTIFICATION

Trade Name (as labeled): BIOPURE MTAD Antibacterial Root Canal Cleanser, Part B
Chemical Name/Classification: BIOPURE MTAD Antibacterial Root Canal Cleanser, Part B
Product Identifier (Part/Item Number): BP36P, BP48P, BP156P, BP288P
U.N. Number: N/A
U.N. Dangerous Goods Classification: N/A
Recommended Use: Material for endodontic disinfecting after instrumentation
Restrictions on Use: For Dental Use Only
Manufacturer/Supplier Name: DENTSPLY Tulsa Dental Specialties
Manufacturer/Supplier Address: 608 Rolling Hills Dr., Johnson City, TN 37604
Manufacturer/Supplier Telephone Number: 1-800-662-1202 (Product Information)
Emergency Contact Telephone Number: 1-800-262-8200
Email address: chemtrec@chemtrec.com

2. HAZARD(S) IDENTIFICATION

Hazard/Danger Classification:

Health	Environmental	Physical
Doxycycline is a broad-spectrum antibiotic used to treat a variety of gram positive and gram negative organisms. This is a Tetracycline Allergy to Tetra.	N/A	N/A

Associated Hazards:

Hazard Statements	Precautionary Statements
Harmful if swallowed. Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation.	Avoid breathing dust / fume / gas / mist / vapors / spray. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do so. Continue rinsing.



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EU Classification: N/A

EU Risk (R) and Safety (S) Phrases: N/A

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Doxycycline Hyclate, USP	24390-14-5	N/A	(67/548/EEC)	100%

Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Remove contact lenses. Immediately flush eyes with plenty of water while holding eyelids apart. Do not use eye ointments.
Skin	Immediately flush skin with plenty of cool soapy water.
Inhalation	Move individual away from exposure into fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen.
Ingestion	If ingestion occurs, flush mouth with water and seek medical attention immediately.
Most important symptoms of exposure	Irritation and/or reddening of eyes, skin or mucous membranes, coughing, shortness of breath.
Other	N/A
Note to Physicians (Treatment, Testing, and Monitoring) N/A	

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	Water spray, alcohol-resistant foam, Carbon dioxide or dry chemical.
Fire Fighting Procedures:	Spray water, alcohol-resistant foam, carbon dioxide or dry chemical aiming at base of flames.
Specific Hazards Arising from the Chemical:	Irritating or toxic decomposition products may be evolved from dried material or container. Emits toxic fumes if burned.
Precautions for Fire Fighters:	Avoid inhalation of smoke. Self-contained breathing apparatus for firefighting if necessary.

Recommended Protective Equipment for Fire Fighters:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
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6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Use personal protective equipment. Avoid breathing dust, vapors, mist or gas. Wipe up with towels immediately to prevent dust of material from being scattered. Discard in trash. Dispose of container and unused contents in accordance with federal, state and local requirements.

Environmental Precautions: N/A

Methods and Materials for Containment and Clean-up: Place in suitable closed containers for disposal by local, state, or federal waste disposal regulations. Avoid generating dust during clean-up.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	SKIN	RESPIRATORY	SKIN

7. HANDLING AND STORAGE

Precautions for Safe Handling: Trained personnel use this product exclusively for dental purposes. Avoid contact with skin and eyes. Avoid generation of dust. Use in well ventilated areas.

Conditions for Safe Storage: Store in ventilated, dry, cool (<22°C/72°F) area out of direct sunlight and away from sources of ignition. Empty bottles may be hazardous because they will retain small amounts of residue; observe warnings.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits: N/A

Biological Exposure Limits: Use in a well-ventilated area.

Appropriate Engineering Controls: N/A

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Individual Protection Measures (PPE)





Specific Eye/face Protection: Wear goggles, safety glasses, or a face shield.

Specific Skin Protection: Wear latex or nitrile gloves. Wear impervious protective clothing, including lab coat, apron or coveralls, as appropriate to prevent skin contact.

Specific Respiratory Protection: Handle the product in a well-ventilated area.

Specific Thermal Hazards: N/A

Recommended Personal Protective Equipment

EYES/FACE	SKIN	RESPIRATORY	SKIN
			

Environmental Exposure Controls: N/A

General Hygiene Considerations and Work Practices: Wear gloves as per universal precautions in dentistry. Wash your hands following use. No eating, drinking or smoking while handling this product.

Protective Measures During Repair and Maintenance of Contaminated Equipment: If aerosols are generated, a disposable dust/mist respirator (N95) may be used.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Yellow crystalline powder	Explosive limits:	N/A
Odor:	Slight	Vapor pressure:	N/A
Odor threshold:	Not known	Vapor density:	Not known
pH:	~3	Relative density:	~1
Melting/freezing point:	200°C / 0°C	Solubility:	50 mg/ml (water)
Initial boiling point and range:	>100°C	Partition coefficient: n-octanol/water:	N/A
Flash point:	N/A	Auto-ignition temperature:	N/A
Evaporation rate:	Not known	Decomposition temperature:	Not known
Flammability:	Not known	Viscosity:	N/A
Explosive Properties:	N/A	Oxidizing Properties:	N/A

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10. STABILITY AND REACTIVITY

Reactivity: Avoid strong oxidizers or water-reactive materials, bases, iron or metal nitrates.

Will corrode copper, zinc, aluminum and their alloys.

Chemical Stability: Stable under recommended storage conditions. Light and Heat sensitive.

Possibility of Hazardous Reactions: Avoid strong oxidizers or water-reactive materials, bases, iron or metal nitrates.

Will corrode copper, zinc, aluminum and their alloys.

Conditions to Avoid: N/A

Incompatible materials: Avoid strong oxidizers or water-reactive materials, bases, iron or metal nitrates.

Will corrode copper, zinc, aluminum and their alloys.

Hazardous Decomposition Products: Decomposition products of the minor components of this compound formed under fire may include potentially hazardous byproducts including carbon dioxide and carbon monoxide, ammonia or oxides of sulfur or nitrogen.

11. TOXICOLOGICAL INFORMATION

Signs and Symptoms of Overexposure: : Irritation of the eyes, nose, throat and lungs, a reduction in plasma calcium concentration that can lead to cardiac arrhythmias and reduced cardiac output.

Emergency Overview:

Likely Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)	LD50 Testing Data (as applicable)	LC50 Testing Data (as applicable)
Eye:	Powder can cause stinging, tearing, redness and pain.	Single	Severe	Acute irritation	Eye	Not known	Not known
Skin:	Can irritate the skin and cause redness, itching and irritation.	Single & Repeated	Severe	Acute irritation	Skin	Not known	Not known
Inhalation:	Can irritate the lungs and mucous membranes and cause coughing and shortness of breath.	Repeated	Severe	Acute irritation	Lungs	Not known	Not known
Ingestion:	Can cause nausea, vomiting, diarrhea and difficulty in swallowing.	Single	Severe	Acute irritation	Stomach	Not known	Not known
Other:	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Medical Conditions Aggravated by Exposure: Allergies to Tetracycline(s).

Carcinogenicity: None

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12. ECOLOGICAL INFORMATION

Toxicity: Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data

LD50 mouse, intravenous = 241 mg/kg

LD50 mouse, intraperitoneal= 410 mg/kg

LD50 rat, intraperitoneal= 378 mg/kg

LD50 dog, intravenous= 100mg/kg

LD50 mammal, intravenous: 5,800 mg/kg

LD50 mouse, oral= 1870 mg/kg

LD50 rat, intravenous= 228 mg/kg

LD50 rat , oral = >2g/kg

LD50 dog, oral= 500 mg/kg

LD50 rat, oral: 34,500 µl/kg

Overexposure may cause reproductive disorder(s) based on tests with laboratory animals. Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

Persistence and Degradability: Not known.

Bio-accumulative Potential: Not known.

Mobility in Soil: Not known.

Other Adverse Effects: Not known.

Results of PBT/vPvB Assessment: Not known.

13. DISPOSAL CONSIDERATIONS

Regulations: Dispose of container and unused contents in accordance with federal, state and local requirements.

Properties (Physical/Chemical) Affecting Disposal: None known

Waste Treatment Recommendations: Discard in trash; do not place in sewer system.

14. TRANSPORT INFORMATION

UN Identification Number: N/A

UN Proper Shipping Name: N/A

Transport hazard class(es): N/A

Packing Group: N/A

Special precautions for user: N/A

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Include as applicable

15. REGULATORY INFORMATION

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): N/A

Toxic Substances Control Act (TSCA): N/A

Clean Water Act (CWA): N/A

Clean Air Act (CAA): N/A

Superfund Amendments and Reauthorization Act (SARA) Title III Information: N/A

SARA Section 311/312 (40 CFR 370) Hazard Categories: N/A

Immediate Hazard:	N/A	Pressure Hazard:	N/A
Delayed Hazard:	emits toxic fumes when burning	Reactivity Hazard:	N/A
Fire Hazard:	N/A		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
N/A	N/A	N/A

State Regulations

California: This product contains the following chemical(s) known to the State of California to cause developmental toxicity, reproductive harm, or birth defects

Components	C.A.S. #	WT %
Doxycycline Hyclate, USP	24390-14-5	100%

International Regulations

Canadian Environmental Protection Act: N/A

Canadian Workplace Hazardous Materials Information System (WHMIS): N/A

European Inventory of Existing Chemicals (EINECS): N/A

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3: To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber or natural latex. The product was not derived from animal products.

This information is based on our present knowledge; however, this shall not constitute a guarantee for specific product features. No toxicity data available for the specific formulation. The health hazard assessment is based on information that is available for its components.

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Date of SDS Preparation/Revision: **07/20/2011**

Data Sources: **Various inc. PubMed database.**