

# SAFETY DATA SHEET Biomox® (amoxicillin) Tablets

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATIONS AND OF THE COMPANY UNDERTAKING

Product Name Biomox® (amoxicillin) Tablets

Recommended use of the chemical and

restrictions on use

**Identified uses**Antibiotic tablets for dogs

**Restrictions on Use** For veterinary use only. Federal law restricts this drug

to use by or on the order of a licensed veterinarian.

Company Identification Virbac AH, Inc.

P.O. Box 162059

(800) 338-3659

Fort Worth, Texas 76161

Customer Information Number

Emergency Telephone Number
Chemtrec Number (800) 424-9300

Other Emergency Number: Poison Control Center: 1-800-222-1222 (human)

HOT LINE NUMBER: 1-800-345-4735 (human and pet)

Issue Date May 27, 2015
Supersedes Date January 30, 2012

Safety Data Sheet prepared in accordance with OSHA's Hazard Communication Standard (29 CFR 1910.1200) and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

#### 2. HAZARDS IDENTIFICATION

#### **Hazard Classification**

This product is classified as not hazardous in accordance with the Globally Harmonized System of Classification and Labelling (GHS).

#### **Label Elements**

Hazard Symbols

None

Signal Word: None

## **Hazard Statements**

None

**Precautionary Statements** 

Prevention

None

Response

None

Storage

None

**Disposal** 

None

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#### 2. HAZARDS IDENTIFICATION

#### **Other Hazards**

Ingestion of this product may cause respiratory and skin sensitization in individuals with penicillin allergies. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon ingestion of this drug.

#### Specific Concentration Limits

The values listed below represent the percentages of ingredients of unknown toxicity.

Acute oral toxicity 1 - 10%
Acute dermal toxicity 40 - 50%
Acute inhalation toxicity 40 - 50%
Acute aquatic toxicity 60 - 70%

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Synonyms:

This product is a mixture.

Component NameCAS NumberConcentrationAmoxicillin Trihydrate61336-70-730 - 40%

Tablets are supplied in 50mg, 100mg and 200mg concentrations.

#### 4. FIRST AID MEASURES

## Description of necessary first-aid measures

#### Eyes

Not an expected route of entry. If tablet contacts eye, flush thoroughly with water. If pain or irritation persists contact a physician.

#### Skin

If irritation develops wash skin thoroughly with soap and water. Obtain medical attention if redness or soreness persists.

#### Ingestion

Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

## Inhalation

Remove person to fresh air. Seek medical attention if symptoms persist.

#### Most important symptoms/effects, acute and delayed

Aside from the information found under Description of necessary first aid measures (above) and Indication of immediate medical attention and special treatment needed, no additional symptoms and effects are anticipated.

## Indication of immediate medical attention and special treatment needed Notes to Physicians

Treat symptomatically.

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#### FIRE - FIGHTING MEASURES

#### **Extinguishing Media**

Use extinguishing media appropriate for surrounding materials.

#### **Unusual Fire and Explosion Hazards**

Can release hazardous vapors during a fire.

#### **Protective Equipment for Fire-Fighting**

Wear full protective clothing and self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

## Personal precautions, protective equipment and emergency procedures

No specific measures recommended.

#### **Environmental Precautions**

Prevent the material from entering drains or watercourses.

## Methods and materials for containment and cleaning up

Pick up and dispose of in accordance with all applicable local and national regulations. Prevent the material from entering drains or watercourses.

#### 7. HANDLING AND STORAGE

## Precautions for safe handling

Wear appropriate protective clothing.

## **Conditions for safe storage**

Store in original container at temperatures between 59°F and 86°F (15°C - 30°C). Store away from children and pets.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## **Control parameters**

Exposure limits are listed below, if they exist.

#### **Amoxicillin Trihydrate**

None established

## Appropriate engineering controls

No specific measures necessary. Good general room ventilation is expected to be adequate to control airborne levels.

## Individual protection measures

## **Respiratory Protection**

Not required under normal conditions of use.

#### Skin Protection

Not required under normal conditions of use. Workers should wash hands before eating, drinking or smoking.

## **Eye/Face Protection**

Not required under normal conditions of use.

## **Body Protection**

Normal work wear

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#### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance** 

Physical State Solid (tablet)

Color White to off-white

Odor No data available
Odor Threshold No data available

pH No data available

Density No data available

No data available

No data available

No data available

**Boiling Range/Point (°C/F)** Melting Point (°C/F) No data available Flash Point (PMCC) (°C/F) Not flammable **Vapor Pressure** No data available No data available **Evaporation Rate (BuAc=1)** Partly soluble Solubility in Water No data available Vapor Density (Air = 1) VOC No data available Partition coefficient (n-Not applicable

octanol/water)

Viscosity

Auto-ignition Temperature

Decomposition Temperature
Upper explosive limit
Lower explosive limit
Flammability (solid, gas)

Not applicable
No data available
No data available
No data available
No data available

## 10. STABILITY AND REACTIVITY

#### Reactivity

Data is not available

#### **Chemical Stability**

Stable under normal conditions.

## Possibility of hazardous reactions

Hazardous polymerization will not occur.

## **Conditions to Avoid**

Heat - high temperatures

#### **Incompatible Materials**

None known.

## **Hazardous Decomposition Products**

Oxides of carbon - nitrogen oxides - sulphur oxides - sodium oxides

#### 11. TOXICOLOGICAL INFORMATION

## **Acute Toxicity**

Amoxicillin:

Oral LD50 (rat) >15,000 mg/kg



#### 11. TOXICOLOGICAL INFORMATION

## Specific Target Organ Toxicity (STOT) - single exposure

No relevant studies identified.

## Specific Target Organ Toxicity (STOT) - repeat exposure

No relevant studies identified.

## Serious Eye damage/Irritation

No relevant studies identified.

## Skin Corrosion/Irritation

No relevant studies identified.

### Respiratory or Skin Sensitization

Amoxicillin: May cause respiratory and skin sensitization in individuals with penicillin allergies. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.

#### Carcinogenicity

Not considered carcinogenic by NTP, IARC, and OSHA.

## **Germ Cell Mutagenicity**

No relevant studies identified.

## **Reproductive Toxicity**

Amoxicillin is rated by the FDA for therapeutic use as Pregnancy Category B: Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

#### **Aspiration Hazard**

Not an aspiration hazard.

## 12. ECOLOGICAL INFORMATION

## **Ecotoxicity**

No relevant studies identified.

#### Mobility in soil

No relevant studies identified.

#### Persistence/Degradability

No relevant studies identified.

## **Bioaccumulative Potential**

No relevant studies identified.

### Other adverse effects

No relevant studies identified.

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#### 13. DISPOSAL CONSIDERATIONS

#### **Disposal Methods**

Dispose of in accordance with all applicable local and national regulations.

#### 14. TRANSPORT INFORMATION

Contact supplier for transport information.

## 15. REGULATORY INFORMATION

#### **United States TSCA Inventory**

This product is a drug and therefore is not regulated under the US EPA Toxic Substance Control Act.

## Canada DSL Inventory

This product is a drug and therefore is not regulated under the Canadian Environmental Protection Act.

## **California Proposition 65**

This product contains the following materials which the State of California has found to cause cancer, birth defects or other reproductive harm: None

#### SARA Title III Sect. 311/312 Categorization

None

#### SARA Title III Sect. 313

This product contains a chemical that is listed in Section 313 at or above de minimis concentrations. The following listed chemicals are present: None

#### 16. OTHER INFORMATION

#### Legend

ACGIH: American Conference of Governmental Industrial Hygienists

BOD: Biological Oxygen Demand

CAS#: Chemical Abstracts Service Number

FIFRA: Federal Insecticide, Fungicide and Rodenticide Act

IARC: International Agency for Research on Cancer

LC50: Lethal Concentration 50%

LD50: Lethal Dose 50%

N/A: Denotes no applicable information found or available

NTP: National Toxicology Program

OSHA: Occupational Safety and Health Administration

PEL: Permissible Exposure Limit STEL: Short Term Exposure Limit TLV: Threshold Limit Value

TSCA: Toxic Substance Control Act

Revision Date: May 27, 2015 Replaces: January 30, 2012

Changes made: Updated to GHS classification.

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#### 16. OTHER INFORMATION

#### **Information Source and References**

This SDS is prepared by Hazard Communication Specialists based on information provided by internal company references.

Prepared By: EnviroNet LLC.

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