

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078354552

N/A



Merck Animal Health  
One Merck Dr.  
Whitehouse Station, NJ 08889

## MATERIAL SAFETY DATA SHEET

Merck Animal Health urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

### SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

**MSDS NAME:** Amoxi-Mast

**SYNONYM(S):** Amoxi-Mast

**MSDS NUMBER:** SP002672

**EMERGENCY NUMBER(S):** Rocky Mountain Poison Center (For Human Exposure):  
(303) 595-4869

Animal Health Technical Services:  
For Animal Adverse Events: Small Animals and Horses: (800) 224-5318  
For Animal Adverse Events: Livestock: (800) 211-3573  
For Animal Adverse Events: Poultry: (800) 219-9286

(908) 423-6000 (24/7/365) English Only  
Emergencies - CHEMTREC:  
(800) 424-9300 (Inside Continental USA)  
(703) 527-3887 (Outside Continental USA)

**INFORMATION:** Animal Health Technical Services:  
For Small Animals and Horses: (800) 224-5318  
For Livestock: (800) 211-3573  
For Poultry: (800) 219-9286

**MERCK MSDS HELPLINE:** (800) 770-8878 (US and Canada)  
(908) 473-3371 (Worldwide)  
Monday to Friday, 9am to 5pm (US Eastern Time)

### SECTION 2. HAZARDS IDENTIFICATION

#### EMERGENCY OVERVIEW

Viscous liquid, in syringe  
Colorless or White  
Characteristic odor  
May cause allergic reaction in sensitive individuals or those allergic to Cephalosporins or Penicillin.  
*May cause effects to:*  
gastrointestinal tract

#### POTENTIAL HEALTH EFFECTS:

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. However, there are data to describe the toxicological properties of the individual ingredients. The following summary is based upon available information about the individual ingredients of the mixture(s), or of the expected properties of the mixture(s).

Amoxicillin, the antibiotic active ingredient in this product, is in the penicillin chemical family. Individuals who are allergic to penicillin antibiotics and are exposed to it by contact with skin, inhalation, or ingestion could experience an allergic reaction, possibly severe.

## LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by OSHA, IARC, NTP or ACGIH are present in concentrations >0.1% in this mixture.

### SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

**CHEMICAL FAMILY:** Antibiotic

**PRODUCT USE:** Veterinary product

**CHEMICAL FORMULA:** Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

### CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	PERCENT
Amoxicillin trihydrate	61336-70-7	0.8

**ADDITIONAL INFORMATION:** This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

### SECTION 4. FIRST AID MEASURES

**INHALATION:** Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

**SKIN CONTACT:** In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

**EYE CONTACT:** In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

**INGESTION:** Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

### SECTION 5. FIRE FIGHTING MEASURES

#### FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

#### SPECIAL FIRE HAZARDS:

Material is combustible and will burn at high temperatures. Emits toxic and corrosive fumes under fire conditions.

#### SPECIAL FIRE FIGHTING PROCEDURES:

Wear full protective clothing and self-contained breathing apparatus (SCBA).

#### SUITABLE EXTINGUISHING MEDIA:

Carbon dioxide (CO<sub>2</sub>), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

#### PERSONAL PRECAUTIONS:

Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

**MSDS NAME:** Amoxi-Mast

**MSDS NUMBER:** SP002672

Latest Revision Date: 06-Sep-2012

Page 2 of 5

**SPILL RESPONSE / CLEANUP:**

All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

**SECTION 7. HANDLING AND STORAGE****HANDLING:**

Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

**STORAGE:**

Store in a cool, dry, well ventilated area. Do not store at temperatures above 20 deg C (68 deg F). Keep in closed tight containers. Keep away from heat, sparks, open flames, and direct sunlight.

**SPECIAL PRECAUTIONS:**

Avoid self-inoculation or needle sticks.

See Section 8 for exposure controls and additional safe handling information.

**SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION****EXPOSURE CONTROLS**

The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

**RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):****Respiratory Protection:**

Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.

**Skin Protection:**

Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.

**Eye Protection:**

Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

**Body Protection:**

In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

**EXPOSURE LIMIT VALUES**

No exposure limits are available for the active ingredient(s) or any other hazardous ingredient in this formulation.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**FORM:** Viscous liquid, in syringe  
**COLOR:** Colorless or White  
**ODOR:** Characteristic odor  
**SOLUBILITY:**  
Water: Slightly soluble

See Section 5 for flammability/explosivity information.

## SECTION 10. STABILITY AND REACTIVITY

**STABILITY/ REACTIVITY:**  
Stable under normal conditions.

**INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:**  
Keep away from heat, sparks, open flame, and direct sunlight.

**HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:**  
No dangerous decomposition is expected if used according to manufacturer's specifications.

## SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below is for the active ingredient(s) in this product.

### ACUTE TOXICITY DATA

**INHALATION:**  
No data available.

**SKIN:**  
No data available.

**EYE:**  
No data available.

**ORAL:**  
Amoxicillin: Oral LD50 > 15000 mg/kg (rat)

**DERMAL AND RESPIRATORY SENSITIZATION:**  
No data available.

### REPEAT DOSE TOXICITY DATA

**SUBCHRONIC / CHRONIC TOXICITY:**  
No data available.

**REPRODUCTIVE / DEVELOPMENTAL TOXICITY:**  
No data available.

**MUTAGENICITY / GENOTOXICITY:**  
No data available.

**CARCINOGENICITY:**  
This material or product has not been evaluated for carcinogenicity.

## SECTION 12. ECOLOGICAL INFORMATION

### ECOTOXICITY DATA

There are no ecotoxicity data available for this product or its components.

### ENVIRONMENTAL DATA

There are no environmental data available for this product or its components.

## SECTION 13. DISPOSAL CONSIDERATIONS

### **MATERIAL WASTE:**

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

### **PACKAGING AND CONTAINERS:**

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

## SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

## SECTION 15. REGULATORY INFORMATION

### **TSCA LISTING**

This material or product is not subject to TSCA requirements.

### **U.S. STATE REGULATIONS**

Check state requirements for ingredient listing.

## SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

### **DEPARTMENT ISSUING MSDS:**

Global Safety & the Environment  
Merck & Co., Inc.  
One Merck Drive  
Whitehouse Station, NJ 08889

### **MERCK MSDS HELPLINE:**

(800) 770-8878 (US and Canada)  
(908) 473-3371 (Worldwide)  
Monday to Friday, 9am to 5pm (US Eastern Time)

### **SIGNIFICANT CHANGES (US SUBFORMAT):**

New regional format

**Amoxicillin Trihydrate Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 12/19/2016
1.1	05/02/2017	1161183-00002	Date of first issue: 12/19/2016

---

**SECTION 1. IDENTIFICATION**

Product name : Amoxicillin Trihydrate Solid Formulation

**Manufacturer or supplier's details**

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road  
Kenilworth - New Jersey - USA 1685

Telephone : 908-740-4000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Veterinary product

---

**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with 29 CFR 1910.1200**

Combustible dust

Respiratory sensitization : Category 1

**GHS label elements**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements : **Prevention:**  
P261 Avoid breathing dust.  
P285 In case of inadequate ventilation wear respiratory protection.  
**Response:**  
P304 + P341 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.

**Amoxicillin Trihydrate Solid Formulation**

Version 1.1      Revision Date: 05/02/2017      SDS Number: 1161183-00002      Date of last issue: 12/19/2016  
Date of first issue: 12/19/2016

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards**

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Hazardous ingredients**

Chemical name	CAS-No.	Concentration (% w/w)
Amoxicillin Trihydrate	61336-70-7	$\geq 70$ - $< 90$
Polyethylene glycol	25322-68-3	$\geq 5$ - $< 10$

**SECTION 4. FIRST AID MEASURES**

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
If not breathing, give artificial respiration.  
If breathing is difficult, give oxygen.  
Get medical attention.
- In case of skin contact : Wash with water and soap.  
Get medical attention if symptoms occur.
- In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists.
- Notes to physician : Treat symptomatically and supportively.



**Amoxicillin Trihydrate Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 12/19/2016
1.1	05/02/2017	1161183-00002	Date of first issue: 12/19/2016

---

---

**SECTION 5. FIRE-FIGHTING MEASURES**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Metal oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
- 

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice and personal protective equipment recommendations.
- Environmental precautions : Discharge into the environment must be avoided.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## Amoxicillin Trihydrate Solid Formulation

Version 1.1      Revision Date: 05/02/2017      SDS Number: 1161183-00002      Date of last issue: 12/19/2016  
 Date of first issue: 12/19/2016

## SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
 Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe dust.  
 Do not swallow.  
 Avoid contact with eyes.  
 Avoid prolonged or repeated contact with skin.  
 Handle in accordance with good industrial hygiene and safety practice.  
 Keep container tightly closed.  
 Minimize dust generation and accumulation.  
 Keep container closed when not in use.  
 Keep away from heat and sources of ignition.  
 Take precautionary measures against static discharges.  
 Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
 Keep tightly closed.  
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Amoxicillin Trihydrate	61336-70-7	TWA	5 mg/m <sup>3</sup> (OEB 1)	Merck
Further information: DSEN, RSEN				
		Wipe limit	0.1 mg/100 cm <sup>2</sup>	Merck
Polyethylene glycol	25322-68-3	TWA (aerosol)	10 mg/m <sup>3</sup>	US WEEL

- Engineering measures : Ensure adequate ventilation, especially in confined areas.  
 Minimize workplace exposure concentrations.  
 Apply measures to prevent dust explosions.  
 Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).  
 Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general

**Amoxicillin Trihydrate Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 12/19/2016
1.1	05/02/2017	1161183-00002	Date of first issue: 12/19/2016

---

limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m<sup>3</sup> - total dust, 5 mg/m<sup>3</sup> - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m<sup>3</sup> - respirable particles, 10 mg/m<sup>3</sup> - inhalable particles.

**Personal protective equipment**

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection  
Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:  
Safety goggles

Skin and body protection : Skin should be washed after contact.

Hygiene measures : Ensure that eye flushing systems and safety showers are located close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.

---

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	: powder
Color	: white
Odor	: characteristic

**Amoxicillin Trihydrate Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 12/19/2016
1.1	05/02/2017	1161183-00002	Date of first issue: 12/19/2016

---

Odor Threshold	:	No data available
pH	:	5.5 - 7.5 (as aqueous solution)
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Solubility(ies) Water solubility	:	1.43 g/l
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

---

**SECTION 10. STABILITY AND REACTIVITY**

**Amoxicillin Trihydrate Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 12/19/2016
1.1	05/02/2017	1161183-00002	Date of first issue: 12/19/2016

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Dust can form an explosive mixture in air. Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

**SECTION 11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure**

Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Ingredients:****Amoxicillin Trihydrate:**

Acute oral toxicity	:	LD50 (Rat): > 8,000 mg/kg
		LD50 (Mouse): > 10,000 mg/kg
		LD50 (Dog): > 3,000 mg/kg

**Polyethylene glycol:**

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity	:	LD50 (Rabbit): > 5,000 mg/kg

Remarks: Based on data from similar materials

**Skin corrosion/irritation**

Not classified based on available information.

**Ingredients:****Polyethylene glycol:**

Species: Rabbit  
Result: No skin irritation  
Remarks: Based on data from similar materials

**Serious eye damage/eye irritation**

Not classified based on available information.

**Amoxicillin Trihydrate Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 12/19/2016
1.1	05/02/2017	1161183-00002	Date of first issue: 12/19/2016

---

**Ingredients:****Polyethylene glycol:**

Species: Rabbit

Result: No eye irritation

Remarks: Based on data from similar materials

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Ingredients:****Amoxicillin Trihydrate:**

Result: Sensitizer

Remarks: May cause sensitization by inhalation.

largely based on human evidence

**Germ cell mutagenicity**

Not classified based on available information.

**Ingredients:****Amoxicillin Trihydrate:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Result: negative

Test Type: Rodent dominant lethal test (germ cell) (in vivo)  
Species: Mouse  
Result: negative

**Polyethylene glycol:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

**Carcinogenicity**

Not classified based on available information.

**IARC**

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**Amoxicillin Trihydrate Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 12/19/2016
1.1	05/02/2017	1161183-00002	Date of first issue: 12/19/2016

**NTP**

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**

Not classified based on available information.

**Ingredients:****Amoxicillin Trihydrate:**

Effects on fertility

: Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 200 mg/kg body weight  
Result: Reduced fertility  
Remarks: Not classified due to inconclusive data.

Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 500 mg/kg body weight  
Result: Reduced fertility  
Remarks: Not classified due to inconclusive data.

Effects on fetal development

: Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL:  $\geq$  1,000 mg/kg body weight  
Result: No embryo-fetal toxicity.

Test Type: Development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: LOAEL: 200 mg/kg body weight  
Result: Some evidence of adverse effects on development, based on animal experiments.  
Remarks: Not classified due to inconclusive data.

Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 200 mg/kg body weight  
Result: Reduced embryonic survival, Reduced offspring weight gain.  
Remarks: Not classified due to inconclusive data.

**Polyethylene glycol:**

Effects on fertility

: Test Type: Reproduction/Developmental toxicity screening test  
Species: Rabbit  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

**Amoxicillin Trihydrate Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 12/19/2016
1.1	05/02/2017	1161183-00002	Date of first issue: 12/19/2016

---

Effects on fetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Ingredients:****Amoxicillin Trihydrate:**

Remarks: Not classified due to inconclusive data.

**Repeated dose toxicity****Ingredients:****Amoxicillin Trihydrate:**

Species: Rat  
Application Route: Oral  
Exposure time: 6 Months  
Remarks: No significant adverse effects were reported

Species: Dog  
Application Route: Oral  
Exposure time: 6 Months  
Remarks: No significant adverse effects were reported

**Polyethylene glycol:**

Species: Rat  
NOAEL: 1,100 mg/kg  
Application Route: Ingestion  
Exposure time: 13 Weeks  
Remarks: Based on data from similar materials

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Ingredients:****Amoxicillin Trihydrate:**

Ingestion : Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhea,  
flatulence, skin rash, Breathing difficulties  
Remarks: May produce an allergic reaction.



**Amoxicillin Trihydrate Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 12/19/2016
1.1	05/02/2017	1161183-00002	Date of first issue: 12/19/2016

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Ingredients:****Amoxicillin Trihydrate:**

Toxicity to fish	:	LC50 (No species specified): 0.035 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to algae	:	EC50 (Selenastrum capricornutum (green algae)): 630 mg/l Exposure time: 72 h  EC50 (Synechococcus leopoliensis (blue-green algae)): 0.0022 mg/l Exposure time: 96 h
M-Factor (Acute aquatic toxicity)	:	100

**Polyethylene glycol:**

Toxicity to fish	:	LC50 (Poecilia reticulata (guppy)): > 100 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
------------------	---	--

**Persistence and degradability****Ingredients:****Amoxicillin Trihydrate:**

Biodegradability	:	Result: Readily biodegradable.
------------------	---	--------------------------------

**Polyethylene glycol:**

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 68 % Exposure time: 28 d Remarks: Based on data from similar materials
------------------	---	--

**Bioaccumulative potential****Ingredients:****Amoxicillin Trihydrate:**

Partition coefficient: n-octanol/water	:	log Pow: -0.124
--	---	-----------------

**Polyethylene glycol:**

Bioaccumulation	:	Species: Fish Bioconcentration factor (BCF): 3.2 Remarks: Based on data from similar materials
-----------------	---	--

**Amoxicillin Trihydrate Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 12/19/2016
1.1	05/02/2017	1161183-00002	Date of first issue: 12/19/2016

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Amoxicillin Trihydrate)

Class : 9

Packing group : III

Labels : 9

**IATA-DGR**

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Amoxicillin Trihydrate)

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 956

Packing instruction (passenger aircraft) : 956

**IMDG-Code**

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Amoxicillin Trihydrate)

Class : 9

Packing group : III

Labels : 9

EmS Code : F-A, S-F

Marine pollutant : yes

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Amoxicillin Trihydrate Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 12/19/2016
1.1	05/02/2017	1161183-00002	Date of first issue: 12/19/2016

**Domestic regulation****49 CFR**

UN/ID/NA number	: UN 3077
Proper shipping name	: Environmentally hazardous substance, solid, n.o.s. (Amoxicillin Trihydrate)
Class	: 9
Packing group	: III
Labels	: CLASS 9
ERG Code	: 171
Marine pollutant	: yes(Amoxicillin Trihydrate)
Remarks	: Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

**SECTION 15. REGULATORY INFORMATION****EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

<b>SARA 311/312 Hazards</b>	: Fire Hazard Acute Health Hazard
-----------------------------	--------------------------------------

<b>SARA 313</b>	: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
-----------------	---

**US State Regulations****Pennsylvania Right To Know**

Amoxicillin Trihydrate	61336-70-7
Sodium glycine carbonate	50610-34-9
Polyethylene glycol	25322-68-3

**California Prop. 65**

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

**The ingredients of this product are reported in the following inventories:**

AICS	: not determined
DSL	: not determined
IECSC	: not determined

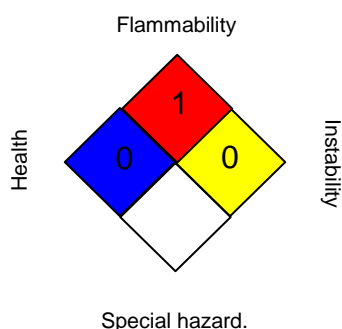
## Amoxicillin Trihydrate Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/19/2016
1.1	05/02/2017	1161183-00002	Date of first issue: 12/19/2016

## SECTION 16. OTHER INFORMATION

## Further information

## NFPA:



## HMIS® IV:

HEALTH	*	0
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

## Full text of other abbreviations

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)  
 US WEEL / TWA : 8-hr TWA

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concern-

**Amoxicillin Trihydrate Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 12/19/2016
1.1	05/02/2017	1161183-00002	Date of first issue: 12/19/2016

---

ing the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 05/02/2017

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

US / Z8