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IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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Emergency telephone number: Emergency telephone number:

Material Name: Anhydrous Ampicillin Hard Capsules

Trade Name: Amplital Hard Capsules

Chemical Family: Mixture

Intended Use: Pharmaceutical product used as antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Magnesium stearate	557-04-0	209-150-3	*
Titanium dioxide	13463-67-7	236-675-5	*
Ampicillin	69-53-4	200-709-7	500 ***

Ingredient	CAS Number	EU EINECS List	%
Gelatin	9000-70-8	232-554-6	*

Additional Information: * Proprietary

*** per tablet/capsule/lozenge/suppository

Ingredient(s) indicated as hazardous have been assessed under standards for workplace

safety.

3. HAZARDS IDENTIFICATION

Appearance: Capsules Signal Word: WARNING

Statement of Hazard: May cause allergic skin and respiratory reaction

May cause allergic reaction in penicillin-sensitive individuals

Additional Hazard Information:

Short Term: Allergic skin reactions might occur following direct contact with this material. Individuals who

are allergic to penicillin antibiotics could have allergic reaction, possibly severe.

Long Term: Repeated inhalation may result in sensitization.

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Known Clinical Effects: Ingestion of this material may cause effects similar to those generally seen in clinical use of

antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. 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. Sensitive individuals who have been exposed to penicillin antibiotics might exhibit allergic reactions, possibly severe. LIFE THREATENING REACTIONS HAVE OCCURRED IN SENSITIVE INDIVIDUALS. In sensitive individuals, symptoms might include

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skin rash, nausea, stomach discomfort, diarrhea, sore or dry mouth or sore tongue.

EU Indication of danger: Harmful

Irritant

EU Hazard Symbols:



EU Risk Phrases:

R42/43 - May cause sensitization by inhalation and skin contact.

Note: This document has been prepared in accordance with standards for workplace safety, which

require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your

workplace.

4. FIRST AID MEASURES

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical

attention.

Skin Contact: Wash skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not

induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-

contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see

Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that

controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of

dry solids. Clean spill area thoroughly.

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Measures for Environmental

Protections:

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to

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avoid environmental release.

Additional Consideration for Large

Spills:

Non-essential personnel should be evacuated from affected area. Report emergency

situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Magnesium stearate

ACGIH Threshold Limit Value (TWA) $= 10 \text{ mg/m}^3 \text{ TWA}$ except stearates of toxic metals

 $= 10 \text{ mg/m}^3 \text{ TWA}$ **Australia TWA**

Titanium dioxide

OSHA - Final PELS - TWAs: $= 15 \text{ mg/m}^3 \text{ TWA}$ total $= 10 \text{ mg/m}^3 \text{ TWA}$ **ACGIH Threshold Limit Value (TWA) Australia TWA** $= 10 \text{ mg/m}^3 \text{ TWA}$

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Ampicillin

Band (OEB):

Pfizer Occupational Exposure OEB 2 - Sensitizer (control exposure to the range of >100ug/m³ to < 1000ug/m³, provide

additional precautions to protect from skin contact)

Analytical method available for Ampicillin. Contact Pfizer Inc for further information. **Analytical Method:**

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process

containment, local exhaust ventilation, or other engineering controls to maintain airborne levels

within the OEB range.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with

large quantities.

Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is Eyes:

possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with

large quantities.

Respiratory protection: None required under normal conditions of use. If airborne exposures are within or exceed the

Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection

factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Hard-gelatin Capsule Color: No data available.

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Molecular Formula: Mixture Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None known

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual

ingredients. The information in this section describes the hazards of various forms of the

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active ingredient.

Acute Toxicity: (Species, Route, End Point, Dose)

Ampicillin trihydrate

Rat Oral LD50 10,000 mg/kg Mouse Oral LD50 15,200 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg Rat Inhalation LC50 > 2000 mg/m³

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg Rat Subcutaneous LD 50 50 mg/kg

Ampicillin

Rat Oral LD 50 > 5000 mg/kg

Rat Intraperitoneal LD 50 4500 mg/kg Mouse Oral LD 50 > 5000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable

at the highest dose used in the test.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Ampicillin trihydrate

103 Week(s) Rat Oral 750 mg/kg/day LOEL Gastrointestinal System 103 Week(s) Mouse Oral 1500 mg/kg/day LOEL Gastrointestinal system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Ampicillin trihydrate

Fertility and Embryonic Development Rat Oral 2500 mg/kg/day LOEL Fetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Ampicillin trihydrate

Bacterial Mutagenicity (Ames) Salmonella Negative
Mammalian Cell Mutagenicity Mouse Lymphoma Negative

Sister Chromatid Exchange Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative

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Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Ampicillin trihydrate

103 Week(s) Mouse Oral 3000 mg/kg/day NOEL Not carcinogenic 103 Week(s) Female Rat Oral 1500 mg/kg/day NOEL Not carcinogenic

103 Week(s) Male Rat Oral 750 mg/kg/day LOEL Malignant tumors, Adrenal gland, Blood

Carcinogen Status: See below

Ampicillin trihydrate

IARC: Group 3

Titanium dioxide

IARC: Group 2B OSHA: Present

Ampicillin

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be

avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Harmful
Irritant

EU Risk Phrases:

R42/43 - May cause sensitization by inhalation and skin contact.

EU Safety Phrases:

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S24 - Avoid contact with skin. S22 - Do not breathe dust.

S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

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OSHA Label:

WARNING

May cause allergic skin and respiratory reaction

May cause allergic reaction in penicillin-sensitive individuals

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

Present
209-150-3

Gelatin

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

XU

Present
232-554-6

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS List

236-675-5

Ampicillin

Australia (AICS): Present
Standard for the Uniform Scheduling Schedule 4

for Drugs and Poisons:

EU EINECS List 200-709-7

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal

Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal

Considerations.

Prepared by: Toxicology and Hazard Communication

Pfizer Global Environment, Health, and Safety

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