1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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Material Name: Anhydrous Ampicillin Children's Oral Drops

Trade Name: Amplital Children's Oral Drops, Solution
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silica colloidal, Ph. Eur.</td>
<td>112945-52-5</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Ampicillin</td>
<td>69-53-4</td>
<td>200-709-7</td>
<td>2 g###</td>
</tr>
<tr>
<td>Potassium metabisulfite</td>
<td>4429-42-9</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Strawberry Oil</td>
<td>Not Assigned</td>
<td>Not listed</td>
<td>0</td>
</tr>
<tr>
<td>Purified water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</td>
<td>*</td>
</tr>
<tr>
<td>Sodium saccharin</td>
<td>128-44-9</td>
<td>204-886-1</td>
<td>*</td>
</tr>
<tr>
<td>Ethylparaben</td>
<td>120-47-8</td>
<td>204-399-4</td>
<td>*</td>
</tr>
<tr>
<td>Saccharin</td>
<td>81-07-2</td>
<td>201-321-0</td>
<td>*</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol 400</td>
<td>25322-68-3</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Monoammonium glycyrrhizinate</td>
<td>53956-04-0</td>
<td>258-887-7</td>
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<tr>
<td>Tartaric acid</td>
<td>87-69-4</td>
<td>201-766-0</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
### per vial/cartridge/ampule.
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Powder plus sterile diluent
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.

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. Based on the effects of other penicillins, in non-allergic individuals large doses are generally non-toxic. 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 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: Fine particles (such as dust and mists) may fuel fires/explosions.

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.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to 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: Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.
Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

The purpose of the Occupational Exposure Band (OEB) is to separate substances into different hazard categories and provide an exposure control and containment strategy for the compound as detailed in this section. The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to alteration when new information becomes available.

Ampicillin

Pfizer Occupational Exposure Band (OEB): OEB 2 - Sensitizer (control exposure to the range of >100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)


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: Wear protective gloves when working with large quantities.
Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is 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: Powder plus sterile diluent
Molecular Formula: Mixture
Color: No data available.
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY
Stability: Stable
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
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 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

**Methylparaben**
- Mouse Oral LD50 > 8000 mg/kg
- Rat Oral LD50 2280 mg/kg

**Polyethylene glycol 400**
- Rat Oral LD50 25 g/kg

**Propylparaben**
- Mouse Oral LD50 6332 mg/kg
- Mouse Intraperitoneal LD50 200 mg/kg

**Sodium saccharin**
- Mouse Oral LD50 17.5 g/kg
- Rat Oral LD50 14.2 - 17 g/kg
- Rat Intraperitoneal LD50 7100 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.

Irritation / Sensitization: (Study Type, Species, Severity)

**Polyethylene glycol 400**
- Eye Irritation Rabbit Mild
- Skin Irritation Rabbit Mild

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

**Propylparaben**
- 3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system
- 4 Week(s) Rat Oral 347.2 g/kg LOAEL Male reproductive system

**Sodium saccharin**
- 36 Week(s) Rat Oral 756 g/kg LOAEL Kidney, Ureter, Bladder
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

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: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Ampicillin trihydrate
IARC: Group 3
Silica colloidal, Ph. Eur.
IARC: Group 3
Sodium saccharin
IARC: Group 3
Saccharin
IARC: Group 3
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.
Material Name: Anhydrous Ampicillin Children’s Oral Drops
Revision date: 02-Jan-2007

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: S24 - Avoid contact with skin.
S22 - Do not breathe dust.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

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

Potassium metabisulfite
Australia (AICS): Present

Purified water
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 231-791-2

Silica colloidal, Ph. Eur.
Australia (AICS): Present

Polysorbate 80
Inventory - United States TSCA - Sect. 8(b) XU
16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.
Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.

End of Safety Data Sheet