# SAFETY DATA SHEETS

## This SDS packet was issued with item:

078920214

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078920215

# Material Safety Data Sheet
# PENTOXIFYLLINE EXTENDED RELEASE TABLETS

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

**Substance Name**
Pentoxifylline ER Tablets, 400mg

**Synonyms**
Not available

**CAS Number**
N/A – This is a drug formulation.
CAS number for the active ingredient, Pentoxifylline is 6493-05-6

**Molecular Formula**
N/A – This is a drug formulation.

**Valeant Pharmaceuticals International, Inc.**
100 LifeSciences Parkway
Steinbach, Manitoba
Canada. R5G 1Z7

**Emergency Phone Numbers:**
Safety Department
1-204-326-9000, Ext. 4333

**Note: This product is intended as a hemorrheologic agent use only through a doctor's recommendation. Please refer to patient info/package insert if available. This MSDS is relative to bulk handling of pentoxifylline and is not intended to supersede patient info/package inserts regarding the safe consumption of this drug.**

## 2. COMPOSITION/ INFORMATION ON INGREDIENTS

| Ingredient | CAS No. | Percentage |
|---|---|---|
| Pentoxifylline | 6493-05-6 | 69% |
| Proprietary Non-Hazardous Ingredients | Unassigned | 31% |

## 3. HAZARDS IDENTIFICATION

***For occupational exposure conditions:***

- When heated to decomposition it emits toxic fumes of nitrous oxides and carbon oxides.
- Slightly flammable in presence of heat
- Potential build-up of static electricity
- Individuals working with chemicals should consider all chemicals to be potentially hazardous even if their individual hazard may be uncharacterized or unknown

## 4. FIRST AID MEASURES

***For occupational exposure conditions:***
Remove from exposure. Remove contaminated clothing.

***Health Risks:*** Overexposure is associated mainly with ingestion and/or contact with the active ingredient of broken tablets.

***After ingestion:*** Flush out mouth with water provided person is conscious. Obtain medical attention.

***After inhalation:*** Remove from exposure to a well-ventilated area. If breathing is difficult give CPR. Seek immediate medical attention. Physical tablet form suggests that risk of inhalation exposure is negligible.

***After skin contact:*** Flush with copious amounts of water. Obtain medical attention.

***After eye contact:*** Check for and remove contact lenses. Immediately flush with running water for 15 minutes, keeping eyelids open. Obtain medical attention.

If irritation persists or signs of toxicity/ hypersensitivity reaction occur, seek immediate medical attention. Provide symptomatic/ supportive care as necessary.

This product is intended as a hemorrheologic agent use only through a doctor's recommendation. Please refer to patient info/package insert if available.

## 5. FIRE FIGHTING MEASURES

***Fire and Explosion Hazards:*** Not expected for the product, although the packaging is combustible

.***Suitable extinguishing media:*** Use water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials

***Special fire fighting procedures:*** As with all fire, evacuate personnel to safe area. For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters.

## 6. ACCIDENTAL RELEASE MEASURES

| | |
|---|---|
| ***Spill or release procedures:*** | Refer to Section 7 and 8 before handling the product. Recover product and place in appropriate container for disposal. Wash area and ventilate if broken product creates dust. For disposal, refer to section 13. Suggested protective clothing may not be sufficient, consult a specialist BEFORE handling this product. |
| ***Small Spill:*** | Vacuum or sweep up spillage. Place spillage in appropriate, labeled container for waste disposal |
| ***Large Spill:*** | Same as for small spillage |

## 7. HANDLING AND STORAGE

***Handling:*** Ground mechanical equipment in contact with dry material. Avoid raising dust. Avoid breaking or crushing tablets. Do not permit eating/ drinking/ smoking near the product. Wash thoroughly after handling. If ingested, seek medical advice immediately and show the container or label. Wash contaminated clothing before reuse.

***Other:*** Follow protective measures provided in Section 8

***Storage:*** Keep in original container tightly closed in a cool (15-30°C) dry place protected from light. Follow product information storage instructions to maintain efficacy.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

***For occupational exposure conditions:***

***Specific control parameter:*** TLV not established

***Personal protective equipment:*** Wear protective clothing and equipment consistent with the degree of Hazard. **RESPIRATORY:** The personal breathing protection will be determined in accordance with IH monitoring results and according to local legislation. **HAND:** Chemically compatible gloves **EYE:** Safety goggles/ glasses **SKIN:** Wear appropriate clothing. At minimum, a N95 particulate respirator is required for direct contact with the powered product. Contact a specialist for more details.

***Industrial Hygiene:*** Use adequate dust control. Do not eat, drink or smoke. Wash thoroughly after handling.

***Special precaution and comments:*** This is a pharmaceutical product and its potential hazard has not been completely characterized. Standard precautionary practices should be followed when handling this substance. Employment of pregnant women is permitted subject to protective measures required by local regulations.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

***Form:*** Film coated tablets

***Appearance:*** White oblong compressed tablet engraved with “BVF” on one side and “0117” on the other side

***Odor:*** Odorless

***Other:*** Bitter tasting

***Melting temperature:*** 105°C (221°F)

| | |
|---|---|
| ***Boiling temperature:*** | 460°C (860°F) |
| ***Ignition temperature:*** | Not applicable |
| ***Flash point:*** | Not applicable |
| ***Explosion limits:*** | Lower not applicable<br>Upper not applicable |
| ***Density (20°C):*** | Not applicable |
| ***Solubility in Organic solvent (20°C):*** | Sparingly soluble in alcohol; freely soluble in chloroform, dichloromethane and methyl alcohol; slightly soluble in ether |
| ***Water (20°C ):*** | Soluble |

## 10. STABILITY AND REACTIVITY

| | |
|---|---|
| ***STABILITY*** | Stable. Hazardous polymerization will not occur. |
| ***CONDITIONS TO BE AVOIDED*** | Light and moisture |
| ***MATERIALS TO BE AVOIDED*** | Strong oxidizers |
| ***HAZARDOUS DECOMPOSITION PRODUCTS*** | When heated to decomposition it emits toxic fumes of nitrous oxides and carbon oxides |

## 11. TOXICOLOGICAL INFORMATION

| | |
|---|---|
| ***$LD_{50}$ oral/ rat:*** | 1170 mg/kg |
| **$LD_{50}$ oral mouse:** | 1225 mg/kg |
| ***Irritancy/ Corrosivity:*** | Skin (rabbit) N/A |
| ***Acute effects on humans:*** | Harmful if swallowed. May cause irritation to skin, eyes, and respiratory system. |
| ***Special remarks:*** | The information described above is applicable during occupational exposure. The outlined preventative measures are not required during therapeutic administration. |

## 12. ECOLOGICAL INFORMATION

No available data

## 13. DISPOSAL CONSIDERATIONS

***Waste Treatment:***
Dispose of waste (product/ packaging) in accordance with all applicable regulatory requirements for pharmaceutical wastes.

***Packaging Treatment:***
Dispose of containers by dispatching to an approved incinerator facility for hazardous waste.

***Disposal Recommendations:***
The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

## 14. TRANSPORT INFORMATION

The MSDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorized persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

TDG Classification: Not controlled under TDG (Canada)

## 15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

Labeling according to EEC Directives

***Name:*** PENTOXIFYLLINE

***Classification:*** Xn

## 16. OTHER INFORMATION

***EC Risk phases:*** R22: Harmful if swallowed

***EC Safety Phrases:*** S36/37/39: Wear suitable protective clothing, gloves, and eye/ face protection

***Uses and Restrictions:*** Pharmaceutical uses

***Training Advice:*** Before using/ handling the product, one must read carefully current MSDS

***Other Special Considerations:*** No additional remarks.

Preparation Date: Dec 07/10

**DISCLAIMER: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Valeant shall not be held liable for any damage resulting from handling or from contact with the above product.**

# Safety Data Sheet

## Section 1: Identification

### Product identifier

**Product Name** • **Pentoxifylline tablet**

**Product Code** • NDC 68682-0101-10; NDC 68682-0101-50

**Product Description** • Prescription pharmaceutical product.

### Relevant identified uses of the substance or mixture and uses advised against

**Recommended use** • Vasotec® is indicated for treatment of hypertension.

**Restrictions on use** • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

### Details of the supplier of the safety data sheet

**Manufacturer** • Valeant Pharmaceuticals International, Inc.

100 LifeSciences Parkway
Steinbach R5G 1Z7
Canada
valeant.com

**Telephone (General)** • 1-800-321-4576

**Supplier** • Oceanside Pharmaceuticals, a division of Valeant Pharmaceuticals N. America, LLC

400 Somerset Corporate Blvd.
Bridgewater, NJ 08807
United States
valeant.com

### Emergency telephone number

**Manufacturer** • 1-800-535-5053 - US - Infotrac

**Manufacturer** • +1 352-323-3500 - International - Infotrac

*This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.*

## Section 2: Hazard Identification

### UN GHS

**According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)**

### Classification of the substance or mixture

**UN GHS** • Acute Toxicity Oral 4
Specific Target Organ Toxicity Single Exposure 1

### Label elements

**UN GHS**

**DANGER**

**Hazard statements** • Harmful if swallowed
Causes damage to organs - Blood

**Precautionary statements**

**Prevention** • Do not handle until all safety precautions have been read and understood.
Avoid breathing dust, fume, gas, mist, vapours and/or spray.
Use personal protective equipment as required.
Wash thoroughly after handling.

**Response** • IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.

**Storage/Disposal** • Store in a well-ventilated place. Keep container tightly closed.

## Other hazards

**UN GHS** • No data available

## Section 3 - Composition/Information on Ingredients

### Substances

• Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

### Mixtures

| Composition | | | |
|---|---|---|---|
| **Chemical Name** | **Identifiers** | **%** | **Classifications According to Regulation/Directive** |
| Hydroxyethyl cellulose | **CAS:**9004-62-0 | N/A | **UN GHS:** Skin Irrit. 2; Eye Irrit. 2A |
| Magnesium stearate | **CAS:**557-04-0<br>**EINECS:**209-150-3 | N/A | **UN GHS:** NDA |
| Pentoxifylline | **CAS:**6493-05-6<br>**EINECS:**229-374-5 | 68.61% | **UN GHS:** NDA |
| Povidone | **CAS:**9003-39-8 | N/A | **UN GHS:** NDA |
| Talc | **CAS:**14807-96-6<br>**EINECS:**238-877-9 | N/A | **UN GHS:** Skin Irrit. 3; STOT RE 1 |

*N/A - Designates that the chemical percentage of composition is not available as it is considered a trade secret.*

## Section 4: First-Aid Measures

### Description of first aid measures

**Inhalation** • Normal use of this product does not pose an inhalation hazard. However, during bulk handling should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.

**Skin** • No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes. Immediately flush skin with large amounts of water. Remove contaminated clothing. Ifirritation (redness, rash, blistering) develops, get medical attention.

**Eye** • IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses,

if present and easy to do. Continue rinsing. Get medical attention immediately if symptoms occur.

**Ingestion**
- Obtain medical attention immediately if ingested.

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

- Symptoms appear to be dose related. Symptoms usually occurred 4 to 5 hours after ingestion and lasted about 12 hours. Symptoms include: flushing, hypotension, convulsions, somnolence, loss of consciousness, fever, and agitation occurred.

### Indication of any immediate medical attention and special treatment needed

**Notes to Physician**
- In addition to symptomatic treatment and gastric lavage, special attention must be given to supporting respiration, maintaining systemic blood pressure, and controlling convulsions. Activated charcoal has been used to absorb pentoxifylline in patients who have overdosed.

**Antidotes**
- The usual treatment for hypotension would be intravenous infusion of normal saline solution. Enalapril may be removed from general circulation by hemodialysis.

## Section 5: Fire-Fighting Measures

### Extinguishing media

**Suitable Extinguishing Media**
- Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

**Unsuitable Extinguishing Media**
- No data available

### Special hazards arising from the substance or mixture

**Unusual Fire and Explosion Hazards**
- No data available

**Hazardous Combustion Products**
- No data available.

### Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

## Section 6 - Accidental Release Measures

### Personal precautions, protective equipment and emergency procedures

**Personal Precautions**
- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

**Emergency Procedures**
- Keep unauthorized personnel away. Clean up spilled tablets and place in sealed container. Avoid breaking tablets or creating dust during clean up.

### Environmental precautions

- No data available on the environmental impact of this product.

### Methods and material for containment and cleaning up

**Containment/Clean-up Measures**
- LARGE SPILLS: Use HEPA vacuum to clean up spill. If HEPA vacuum is not available, dampen spilled tablets with water prior to cleaning up to prevent dust cloud.

## Section 7 - Handling and Storage

### Precautions for safe handling

**Handling**
- Avoid breaking or crushing tablets. Minimize dust generation and accumulation. Use good safety and industrial hygiene practices.

## Conditions for safe storage, including any incompatibilities

**Storage**

- Keep tightly closed. Store at controlled room temperature 25ºC/77ºF (excursions permitted to 15-30ºC/59-86ºF), to maintain product integrity. Use before date marked on carton and/or container. Protect from light.

# Section 8 - Exposure Controls/Personal Protection

## Control parameters

**Exposure Limits/Guidelines**

- Refer to the occupational exposure limits / guidelines for the individual product components.

| Exposure Limits/Guidelines | | | | | |
|---|---|---|---|---|---|
| | **Result** | **ACGIH** | **Canada Quebec** | **NIOSH** | **United States - New York** |
| Talc (14807-96-6) | TWAs | 2 mg/m3 TWA (particulate matter containing no asbestos and <1% crystalline silica, respirable fraction) | 3 mg/m3 TWAEV (respirable dust) | 2 mg/m3 TWA (containing no Asbestos and <1% Quartz, respirable dust) | 2 mg/m3 TWA (containing no asbestos, respirable dust) |

**Exposure Control Notations**

**ACGIH**

•Talc (14807-96-6): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (containing no asbestos fibers))

**Exposure Limits Supplemental**

**OSHA**

•Talc (14807-96-6): **Mineral Dusts:** (20 mppcf TWA (if 1% Quartz or more, use Quartz limit))

**ACGIH**

•Talc (14807-96-6): **TLV Basis - Critical Effects:** (pulmonary fibrosis (containing no asbestos fibers); pulmonary function (containing no asbestos fibers))

## Exposure controls

**Engineering Measures/Controls**

- NO SPECIAL CONTROLS ARE REQUIRED UNDER CONDITIONS OF INTENDED USE. Local exhaust ventilation should be provided when handling bulk product.

**Personal Protective Equipment**

**Respiratory**

- For bulk handling, the personal breathing protection should be determined based upon a risk assessment and in accordance with local regulations. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

**Eye/Face**

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging.

**Hands**

- Wear protective gloves when handling bulk product before closed in final packaging.

**Skin/Body**

- Avoid contact with skin.

**General Industrial Hygiene Considerations**

- Handle in accordance with good industrial hygiene and safety practice. Wash thoroughly with soap and water after handling.

**Environmental Exposure Controls**

- No data available

# Section 9 - Physical and Chemical Properties

## Information on Physical and Chemical Properties

| Material Description | | | |
|---|---|---|---|
| Physical Form | Solid | Appearance/Description | white, oblong compressed tablet. |
| Color | White | Odor | No odor. |
| Odor Threshold | Not relevant | | |
| **General Properties** | | | |
| Boiling Point | No data available | Melting Point/Freezing Point | No data available |
| Decomposition Temperature | No data available | pH | Not relevant |
| Specific Gravity/Relative Density | No data available | Water Solubility | Soluble |
| Viscosity | Not relevant | | |
| **Volatility** | | | |
| Vapor Pressure | Not relevant | Vapor Density | Not relevant |
| Evaporation Rate | Not relevant | | |
| **Flammability** | | | |
| Flash Point | Not relevant | UEL | Not relevant |
| LEL | Not relevant | Autoignition | Not relevant |
| Flammability (solid, gas) | Not relevant | | |
| **Environmental** | | | |
| Octanol/Water Partition coefficient | No data available | | |

## Section 10: Stability and Reactivity

### Reactivity

- Stable under normal temperatures and pressures.

### Chemical stability

- Hazardous polymerization will not occur.

### Possibility of hazardous reactions

- No data available

### Conditions to avoid

- Excessive heat or moisture.

### Incompatible materials

- Strong oxidizing agents.

### Hazardous decomposition products

- Nitrous oxides. Irritating and/or toxic fumes or gases.

## Section 11 - Toxicological Information

### Information on toxicological effects

| Components | | |
|---|---|---|
| Pentoxifylline (68.61%) | 6493-05-6 | **Acute Toxicity:** Ingestion/Oral-Mouse LD50 • 1225 mg/kg; Ingestion/Oral-Rat LD50 • 1170 mg/kg; *Behavioral*:**Changes in motor activity (specific assay)**; *Lungs, Thorax, or Respiration*:**Respiratory depression** |

| GHS Properties | Classification |
|---|---|
| **Acute toxicity** | **UN GHS** • Acute Toxicity - Oral 4 |
| **Skin corrosion/Irritation** | **UN GHS** • Classification criteria not met |

| | |
|---|---|
| **Serious eye damage/Irritation** | **UN GHS** • Classification criteria not met |
| **Skin sensitization** | **UN GHS** • Classification criteria not met |
| **Respiratory sensitization** | **UN GHS** • Classification criteria not met |
| **Aspiration Hazard** | **UN GHS** • Classification criteria not met |
| **Carcinogenicity** | **UN GHS** • Classification criteria not met |
| **Germ Cell Mutagenicity** | **UN GHS** • Classification criteria not met |
| **Toxicity for Reproduction** | **UN GHS** • Classification criteria not met |
| **STOT-SE** | **UN GHS** • Specific Target Organ Toxicity Single Exposure 1 |
| **STOT-RE** | **UN GHS** • Classification criteria not met |

**Target Organs**
- Blood

### Potential Health Effects

#### Inhalation

**Acute (Immediate)**
- Under normal conditions of use, no health effects are expected. Exposure to dust from broken tablets may cause irritation.

**Chronic (Delayed)**
- Repeated and prolonged exposure may cause irritation.

#### Skin

**Acute (Immediate)**
- Under normal conditions of use, no health effects are expected.

**Chronic (Delayed)**
- Repeated and prolonged exposure may cause irritation.

#### Eye

**Acute (Immediate)**
- May cause mild eye irritation with direct contact to eye.

**Chronic (Delayed)**
- Under normal conditions of use, no health effects are expected.

#### Ingestion

**Acute (Immediate)**
- Blood thinner which in doses exceeding prescription level increase risk of hemorrhage. Toxic if ingested in excess of prescription dose.

**Chronic (Delayed)**
- No data available

| Carcinogenic Effects | | | |
|---|---|---|---|
| | **CAS** | **IARC** | **NTP** |
| Povidone | 9003-39-8 | Group 3-Not Classifiable | Not Listed |
| Talc | 14807-96-6 | Group 3-Not Classifiable | Evidence of Carcinogenicity |

## Section 12 - Ecological Information

### Toxicity

- This material has not been tested for environmental effects.

### Persistence and degradability

- No data available

### Bioaccumulative potential

- No data available

### Mobility in Soil

- No data available

### Other adverse effects

## Section 13 - Disposal Considerations

### Waste treatment methods

**Product waste**
- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

**Packaging waste**
- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

## Section 14 - Transport Information

| | UN number | UN proper shipping name | Transport hazard class (es) | Packing group | Environmental hazards |
|---|---|---|---|---|---|
| **DOT** | Not Applicable | Not Regulated | Not Applicable | Not Applicable | |
| **TDG** | Not Applicable | Not Regulated | Not Applicable | Not Applicable | |
| **IMO/IMDG** | Not Applicable | Not Regulated | Not Applicable | Not Applicable | |
| **IATA/ICAO** | Not Applicable | Not Regulated | Not Applicable | Not Applicable | |

**Special precautions for user**
- No data available

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
- No data available

## Section 15 - Regulatory Information

### Safety, health and environmental regulations/legislation specific for the substance or mixture

**SARA Hazard Classifications**
- No data available

| Inventory | | | | |
|---|---|---|---|---|
| **Component** | **CAS** | **Canada DSL** | **EU EINECS** | **TSCA** |
| Hydroxyethyl cellulose | 9004-62-0 | Yes | No | Yes |
| Povidone | 9003-39-8 | Yes | No | Yes |
| Magnesium stearate | 557-04-0 | Yes | Yes | Yes |
| Talc | 14807-96-6 | Yes | Yes | Yes |
| Pentoxifylline | 6493-05-6 | No | Yes | No |

### Canada

**Labor**

**Canada - WHMIS - Classifications of Substances**

| | | |
|---|---|---|
| • Magnesium stearate | 557-04-0 | Not Listed |
| • Talc | 14807-96-6 | D2A |
| • Hydroxyethyl cellulose | 9004-62-0 | Uncontrolled product according to WHMIS classification criteria |
| • Pentoxifylline | 6493-05-6 | Not Listed |
| • Povidone | 9003-39-8 | Uncontrolled product according to WHMIS classification criteria (listed under Providone) |

## United States - California

### Environment

**U.S. - California - Proposition 65 - Carcinogens List**

| | | |
|---|---|---|
| • Magnesium stearate | 557-04-0 | Not Listed |
| • Talc | 14807-96-6 | Not Listed |
| • Hydroxyethyl cellulose | 9004-62-0 | Not Listed |
| • Pentoxifylline | 6493-05-6 | Not Listed |
| • Povidone | 9003-39-8 | Not Listed |

**U.S. - California - Proposition 65 - Developmental Toxicity**

| | | |
|---|---|---|
| • Magnesium stearate | 557-04-0 | Not Listed |
| • Talc | 14807-96-6 | Not Listed |
| • Hydroxyethyl cellulose | 9004-62-0 | Not Listed |
| • Pentoxifylline | 6493-05-6 | Not Listed |
| • Povidone | 9003-39-8 | Not Listed |

**U.S. - California - Proposition 65 - Reproductive Toxicity - Female**

| | | |
|---|---|---|
| • Magnesium stearate | 557-04-0 | Not Listed |
| • Talc | 14807-96-6 | Not Listed |
| • Hydroxyethyl cellulose | 9004-62-0 | Not Listed |
| • Pentoxifylline | 6493-05-6 | Not Listed |
| • Povidone | 9003-39-8 | Not Listed |

**U.S. - California - Proposition 65 - Reproductive Toxicity - Male**

| | | |
|---|---|---|
| • Magnesium stearate | 557-04-0 | Not Listed |
| • Talc | 14807-96-6 | Not Listed |
| • Hydroxyethyl cellulose | 9004-62-0 | Not Listed |
| • Pentoxifylline | 6493-05-6 | Not Listed |
| • Povidone | 9003-39-8 | Not Listed |

## Section 16 - Other Information

**Revision Date**
- 22/February/2016

**Last Revision Date**
- 22/February/2016

**Preparation Date**
- 22/February/2016

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