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 **EINECS:**209-150-3	N/A	**UN GHS:** NDA
Pentoxifylline	**CAS:**6493-05-6 **EINECS:**229-374-5	68.61%	**UN GHS:** NDA
Povidone	**CAS:**9003-39-8	N/A	**UN GHS:** NDA
Talc	**CAS:**14807-96-6 **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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