SAFETY DATA SHEETS

This SDS packet was issued with item:

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N/A

ani Pharmaceuticals, Inc.

SAFETY DATA SHEET

Product Name: Pentoxifylline Extended-Release Tablet, USP 400mg

Version: 00

Issued Date: December 19, 2023

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(Date)

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(Date)

Approved By: [signature] 12/19/2023

(Quality Assurance) **(Date)**

ani Pharmaceuticals, Inc.

SAFETY DATA SHEET

1. **Identification:**

Product Identifier: Pentoxifylline Extended-Release Tablet, USP 400mg

Other means of Identification Synonyms: Not available

Recommended use: 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 medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions: No other uses are advised.

Manufacturer: Novitium Pharma LLC
70 Lake Drive, East Windsor, NJ – 08520
Online Assistance: www.novitiumpharma.com

2. **Hazard(s) Identification:**

Pharmaceutical Agent – *Handling of this product in its final form presents minimal occupational exposure risk*

GHS Classification: Acute Toxicity Oral 4
Specific Target Organ Toxicity Single Exposure 1

OSHA Specific - Classification: Not classified

Label Elements:

Signal Word: Danger

Hazard Statement: Harmful if swallowed
Causes damage to organs - Blood

Precautionary Statement:

Prevention: Do not handle until all safety precautions have been read and understood.
Avoid breathing dust, fume, gas, mist, vapors 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.

Disposal: Store in a well-ventilated place. Keep container tightly closed.

Hazard(s) Not Otherwise Classified (HNOC): Not classified

3. **Composition/Information on Ingredients:**

Chemical Name	CAS Number
Pentoxifylline	6493-05-6
Hydroxypropyl methyl cellulose (Hypromellose)	9004-65-3
Povidone K30, NF	9003-39-8

4. **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 Contact: 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. If irritation develops, get medical attention.

Eye Contact: Flush with running water for several minutes. If eye irritation persists, get medical attention.

Ingestion: If swallowed, rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Immediate consultation with medical personnel is advised.

Information for doctor:
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
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. The usual treatment for hypotension would be intravenous infusion of normal saline solution. Enalapril may be removed from general circulation by hemodialysis.

5. **Fire-Fighting Measures:**

Suitable Extinguishing Media: Use firefighting measures that suit the environment. Water spray, Carbon dioxide (CO_2). Foam. Dry powder. Halons.

Unsuitable Extinguishing Media: No data available.

Specific Hazards Arising from the Chemical: No data available

Hazardous Combustion: No information available

Fire/Explosion Hazards: No information available.

Special Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. **Accidental Release Measures:**

Personal Precautions, Protective Equipment and Emergency Procedures: As instructed in Section 8

Environmental precautions: No data available

Methods and Materials for Containment and Cleaning Up: 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.

Additional Consideration for Large Spills: Cleaning operations should only be undertaken by trained personnel. Keep unauthorized personnel away. Clean up spilled tablets and place in sealed container. Avoid breaking tablets or creating dust during clean up.

7. **Handling and Storage:**

Precautions for Safe Handling: No special precautions are necessary if used correctly. Avoid breaking or crushing tablets. Minimize dust generation and accumulation. Use good safety and industrial hygiene practices.

Conditions for Safe Storage, Including Any Incompatibilities: Keep tightly closed. Store at controlled room temperature 25°C/77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container. Protect from light.

8. **Exposure Control/Personal Protection:**

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Biological Limit Values: No biological exposure limits noted for the ingredient(s).

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

Individual Protection Measures, Such as Personal Protective Equipment

Eye/Face Protection: Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging.

Skin Protection Hand Protection: Wear protective gloves when handling bulk product before closed in final packaging. Avoid contact with skin.

Other: For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities

are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory Protection: 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.

Thermal Hazards: Not available.

General Hygiene Considerations: Handle in accordance with good industrial hygiene and safety practice. Wash thoroughly with soap and water after handling.

9. **Physical and Chemical Properties:**

Appearance	Yellow, oblong film coated tablets embossed with 'N668' on one side and plain on the other side
Physical state	Tablet
Odor	Characteristic
Solubility	Practically soluble in water.

10. **Stability and Reactivity:**

Reactivity:	Stable under normal temperatures and pressures.
Chemical Stability:	Hazardous polymerization will not occur.
Possibility of Hazardous Reaction:	No Data available
Condition to Avoid:	Excessive heat or moisture.
Incompatible Materials:	Strong oxidizing agents.
Corrosivity:	No data available.
Polymerization:	No data available.

11. **Toxicological information:**

Information on likely routes of exposure:

Ingestion:	Blood thinner which in doses exceeding prescription level increase risk of hemorrhage. Toxic if ingested more than prescription dose.
Inhalation:	Under normal conditions of use, no health effects are expected. Exposure to dust from broken tablets may cause irritation. Repeated and prolonged exposure may cause irritation.
Skin Contact:	Under normal conditions of use, no health effects are expected. Repeated and prolonged exposure may cause irritation.
Eye Contact:	May cause mild eye irritation with direct contact to eye. Under normal conditions of use, no health effects are expected.

Cross Sensitivity: No sensitizing effect known

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**

12. Ecological Information:

Ecotoxicity	This product is not tested for environmental hazard.
BOD5 and COD	Not available.
Products of biodegradation	Not available.
Toxicity products of degradation	Not available.

13. Disposal considerations:

Disposal Instructions: Dispose of contents/container in accordance with local/regional/national/international regulations.

Local Disposal Regulations: Dispose in accordance with all applicable regulations.

Hazardous Waste Code: The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from Residues / Unused Products: Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Contaminated Packaging: Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

14. Transport information:

DOT	Not regulated as dangerous goods.
UN Number	Not available (for finished dosage form).
UN Shipping name	Not available (for finished dosage form).
Transport hazard class	Not available (for finished dosage form).
Packing group	Not available (for finished dosage form).
Environmental hazard	Not available (for finished dosage form).
Transport in Bulk	Not available (for finished dosage form).
Special precautions needed with transport	Not available (for finished dosage form).

15. Regulatory information:

No relevant information available

16. Other information:

Reference: 1. Pentoxifylline Tablets, USP Material Safety data sheet, Valeant Pharmaceuticals International Inc.,

Special Considerations: Not Available.

Issue date: December 19,2023

Version # 00

Disclaimer: The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

This Safety Data Sheet is prepared as a reference document in consultation with the safety data sheet prepared by the API manufacturer. The hazards outlined are based on quantity, duration, and type of exposure and may not be reflective of the product finished dosage form.

Revision History

Version 00: Date 12/19/2023