

SAFETY DATA SHEETS

This SDS packet was issued with item:

078939318

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

078926668 078926670 078926674 078937211 078939320 078939323 078939325 078939326




SAFETY DATA SHEET

Product Name: PredniSONE Tablets, USP 1mg, 2.5mg, 5mg, 10mg, 20mg, 50mg

Version: 00

Issued Date: November 19, 2019

Prepared By:  11/19/2019
(Date)

Reviewed By:  11/19/2019
(Date)

Approved By:  11/19/19
(Quality Assurance) (Date)

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1. Identification:

Product Identifier: PredniSONE Tablets, USP

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:

GHS Classification: Not classified

OSHA Specific - Classification: Not classified.

Label Elements

Signal Word: Warning

Hazard Statement: This product is intended for use only if prescribed by a licensed health care professional. If any person using this product experiences adverse health effects, they should seek medical treatment.

Precautionary Statement

Prevention: Wear the appropriate protective equipment, and maintain good industrial hygiene practices.

Response: Wash hands after handling this product.

Disposal: Dispose of contents/container to an approved disposal site.

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

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3. Composition/Information on Ingredients:

Chemical Name	CAS Number
Prednisone, USP (Micronized)	53-03-2
Lactose Monohydrate, NF 200 MSH	64044-51-5
Microcrystalline Cellulose, NF	9004-34-6
Pregelatinized Starch, NF	9005-25-8
Sodium Lauryl Sulfate, NF	151-21-3
Sodium Starch Glycolate, NF	9063-38-1
Magnesium Stearate, NF	557-04-0

4. First-aid measures:

General Information:

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222.

Inhalation: Move to fresh air and have the patient rest. Call a physician if symptoms develop or persist.

Skin Contact: Remove contaminated clothing and rinse affected area liberally with water and soap. Get medical attention if irritation persists.

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

Ingestion: Thoroughly rinse mouth with water. **IF SWALLOWED:** Call a POISON CENTER or doctor/physician if you feel unwell.

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5. Fire-Fighting Measures:

Suitable Extinguishing Media: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Unsuitable Extinguishing Media: Water jet is not a suitable extinguishing media as it will spread the fire.

Specific Hazards Arising from the Chemical:

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

Fire/Explosion Hazards: No information available.

Special Protective Equipment and Precautions for Firefighters: Wear suitable protective equipment.

Fire-Fighting Equipment/Instructions: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

6. Accidental Release Measures:

Personal Precautions, Protective Equipment and Emergency Procedures: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation to avoid formation of dust. Wear appropriate personal protective equipment.

Methods and Materials for Containment and Cleaning Up: If it is safe, contain the source of the spill. Collect spillage in suitable, appropriately labeled container for disposal. Avoid dust generation. Clean spill site thoroughly. Do not allow the substance to enter sewers or ground water.

Additional Consideration for Large Spills: Cleaning operations should only be undertaken by trained personnel. Evacuate all non-essential personnel.

7. Handling and Storage:

Precautions for Safe Handling: Avoid contact with clothing, skin, and eyes and wash hands thoroughly after handling.

Conditions for Safe Storage, Including Any Incompatibilities: This material should be handled and stored per label instructions to ensure product integrity.

Store between 15° to 30 °C (59° to 86°F).

8. Exposure Control/Personal Protection:

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

Appropriate Engineering Controls: Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent

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materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual Protection Measures, Such as Personal Protective Equipment

Eye/Face Protection: Safety glasses with side shields are recommended in laboratory, medical, or industrial settings. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin Protection Hand Protection: Chemically compatible gloves for laboratory, medical, or industrial settings. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

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: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal Hazards: Not available.

General Hygiene Considerations: Handle in accordance with good industrial hygiene and safety practice.

9. Physical and Chemical Properties:

Appearance	White to off-white.
Physical state	Tablet.
Odor	No data available.
Solubility	Partially soluble in water.

10. Stability and Reactivity:

Reactivity:	Stable at normal conditions.
Chemical Stability:	Stable at normal conditions.
Possibility of Hazardous Reaction:	No dangerous reaction known under conditions of normal use.
Condition to Avoid:	Contact to incompatible materials. Avoid dust accumulation and dispersal into the air.
Incompatible Materials:	Strong oxidizing agents.
Corrosivity:	No data available.
Polymerization:	No data available.

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11. Toxicological information:

Information on likely routes of exposure:

Ingestion:	Anaphylactoid or hypersensitivity reactions may occur.
Inhalation:	Due to lack of data the classification is not possible.
Skin Contact:	No irritating effects known.
Eye Contact:	No irritating effect known.
Cross Sensitivity:	No sensitizing effects known.
Acute Toxicity:	May be harmful if swallowed in large quantities.

12. Ecological Information:

Ecotoxicity	Not available.
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: Not available.

Hazardous Waste Code: Not regulated.

Waste from Residues / Unused Products: Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated Packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information:

DOT	Not available.
UN Number	Not available.
UN Shipping name	Not available.
Transport hazard class	Not available.
Packing group	Not available.
Environmental hazard	Not available.
Transport in Bulk	Not available.
Special precautions needed with transport	Not available.

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15. Regulatory information:

No data available – a Chemical Safety Assessment has not been conducted.

Reference: 1. SDS of PredniSONE Tablets, USP 1mg, 2.5mg, 5mg, 10mg, 20mg, 50mg (West-Ward Pharmaceuticals Corporation)

Other Special Considerations: Not Available.

Issue date: November 19, 2019

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.