

SAFETY DATA SHEETS

This SDS packet was issued with item:

078949019

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

078949020 078949022

SAFETY DATA SHEET

1. Identification:

Product Identifier: Misoprostol Tablets, USP 100mcg; 200mcg

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: Not classified

OSHA Specific - Classification: Not classified.

Label Elements

Signal Word: Danger



Hazard Statement: H360FD – may damage fertility, may damage the unborn child

Precautionary Statement:

P201 – Obtain special instructions before use
P202 – Do not handle until all safety precautions have been read and understood
P281 – use personal protective equipment as required
P308 + P313 – if exposed or concerned, get medical attention/advice
P405 – store locked up
P501 – dispose of contents/container in accordance with all local and national regulations

Prevention Not classified

Response: Not classified

Disposal: Please refer to Section 7 for Storage and Section 13 for Disposal information.

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

3. Composition/Information on Ingredients:

Chemical Name	CAS Number
Misoprostol, USP	59122-46-2
Microcrystalline cellulose, NF	9004-34-6
Sodium starch glycolate Type A, NF	9063-38-1
Hydrogenated Vegetable Oil, Type 1, NF	68334-28-1

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: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

Skin Contact: Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

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

Ingestion: Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

5. Fire-Fighting Measures:

Suitable Extinguishing Media: Water spray, water foam, polymer foam carbon dioxide, dry chemical powder

Unsuitable Extinguishing Media: No data available.

Specific Hazards Arising from the Chemical: No data available.

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Hazardous Combustion: No information available.

Fire/Explosion Hazards: No information available.

Special Protective Equipment and Precautions for Firefighters: In case of fire, watch out for formation of toxic smoke and gases. Wear suitable protective equipment. Prevent contact with skin and eyes.

Fire-Fighting Equipment/Instructions: As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

6. Accidental Release Measures:

Personal Precautions, Protective Equipment and Emergency Procedures: Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

Methods and Materials for Containment and Cleaning Up: Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.

Additional Consideration for Large Spills: Cleaning operations should only be undertaken by trained personnel.

7. Handling and Storage:

Precautions for Safe Handling: Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure.

Conditions for Safe Storage, Including Any Incompatibilities: Keep container tightly closed. Store in accordance with information listed on the product insert. **Store between 20° to 25°C (68° to 77°F).**

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: Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

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.

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Skin Protection Hand Protection: Long sleeved clothing. Chemical resistant apron. 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. When using, do not eat, drink or smoke. Avoid contact with skin, eyes and clothing. Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower. Wash hands before breaks and immediately after handling the product. Do not take internally.

9. Physical and Chemical Properties:

Appearance	White
Physical state	Tablet
Odor	Odorless
Solubility	No data available

10. Stability and Reactivity:

Reactivity:	No data available.
Chemical Stability:	Stable at normal conditions.
Possibility of Hazardous Reaction:	None under normal processing.
Condition to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions
Incompatible Materials:	Strong oxidizing agents.
Corrosivity:	No data available.
Polymerization:	No data available.

11. Toxicological information:

Information on likely routes of exposure:

Ingestion:	Based on available data, the classification criteria are not met.
Inhalation:	Not an expected route of exposure.
Skin Contact:	Not an expected route of exposure.
Eye Contact:	Not an expected route of exposure.
Cross Sensitivity:	No data available.
Acute Toxicity:	No data available.

12. Ecological Information:

Ecotoxicity	Not available.
BOD5 and COD	Not available.
Products of biodegradation	Not available.

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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: Dispose of as above.

Contaminated Packaging: Dispose of as above.

14. Transport information:

DOT	Not available (for finished dosage form).
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 data available – a Chemical Safety Assessment has not been conducted.

Misoprostol:

CERCLA/SARA 313 Emission reporting	Not listed.
California Proposition 65	Developmental toxicity 4/1/1990.
Standard for the Uniform Scheduling for Drugs and Poisons	Schedule 4.
EU EINECS/ELINCS List	Not listed.

16. Other information:

Reference: 1. Misoprostol Tablets SDS (Pfizer)

Special Considerations: Not Available.

Issue date: October 12, 2023

Version # 01

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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 01: Date 10/12/2023