



SAFETY DATA SHEET (SDS)

1. PRODUCT AND COMPANY INFORMATION

Product Name: Misoprostol 1% HPMC Dispersion
Manufacturer Information
Company Name: Chirogate International Inc.
Headquarters: No. 2, Shih 4th Rd., Yangmei Dist., Taoyuan City 32657, Taiwan
Emergency Contact: Office Hours: +886-3-496-3808
Non-Office Hours: +886-975-527-768
Fax: +886-3-496-3800
Email: kirogate@ms63.hinet.net

2. HAZARDS IDENTIFICATION

GHS Hazards Classification (According to Regulation (EC) No. 1272/2008)

Repr. 1B H360 May damage fertility or the unborn child.

GHS Hazards Identification (According to Regulation (EC) No. 1272/2008)

Signal Word Danger

GHS Hazard Statement H360: May damage fertility or the unborn child.

GHS Precautionary Statement P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and understood.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P308+P313: If exposed or concerned : Get medical advice/attention.

P405 : Store locked up.

Unclassified Hazards/Hazards Not Otherwise Classified

No data available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Composition:

Misoprostol HPMC 1% Dispersion (CAS Number 103601-27-0) is made up of the following components.

Composition	Concentration (w/w)
Misoprostol	1%
Hydroxypropylmethylcellulose 2910	99%

CAS Number:

Composition	CAS Number
Misoprostol HPMC 1% Dispersion	103601-27-0
Misoprostol	59122-46-2
Hydroxypropylmethylcellulose 2910	9004-65-3

Synonyms: (\pm)-Methyl-(1*R*,2*R*,3*R*)-3-hydroxy-2-[(*E*)-(4*RS*)-4-hydroxy-4-methyl-1-octenyl]-5-oxocyclopentaneheptanoate 1%
Hydroxypropylmethylcellulose Dispersion

Chemical Formula: C₂₂H₃₈O₅ · x Hypromellose



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4. FIRST-AID MEASURES

Description of First Aid Measures

General Advice

If medical attention is required, show this safety data sheet to the doctor.

If Inhaled

If inhaled, move person to fresh air. If not breathing, give artificial respiration and consult a physician.

In Case of Skin Contact

Wash affected area with soap and water. Consult a physician if any exposure symptoms are observed.

In Case of Eye Contact

Immediately rinse eyes with plenty of water for at least 15 minutes. Consult a physician.

If Swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Do NOT induce vomiting unless advised to do so by a physician or Poison Control Center. Seek medical attention.

Most Important Symptoms and Effects, Both Acute and Delayed

The most important known symptoms and effects are described in Section 2 and/or section 11.

Indication of any Immediate Medical Attention and Special Treatment Needed

No data available

5. FIRE FIGHTING MEASURES

Extinguishing Media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special Hazards Arising from the Substance

Carbon oxides

Advice for Firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

Further Information

No data available

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Method and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.



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7. HANDLING AND STORAGE

Handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

Storage

This substance should store in airtight and light-resistant packages. Keep refrigerated at temperature of 2~8°C for long-term storage.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

General

This product should be handled with personal protective equipment. Avoid inhalation. Avoid all contact. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Wash the skin after the finishing of the work with water and soap carefully.

Control Parameters

Contains no components with established occupational exposure limits.

Personal protective equipment

Respiratory protection: mask with active carbon filter

Hand Protection: chemical-resistant gloves

Eye protection: safety goggles

Skin protection: protective clothing

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	White to off-white powder.
Odour	No data available
Odour Threshold	No data available
pH	No data available
Melting Point	No data available
Boiling Point	No data available
Flammability (Solid/Gas)	No data available
Decomposition Temp.	No data available
Flash point	No data available
Auto-Ignition Temp.	No data available
Explosive Limits	No data available
Vapour Pressure	No data available
Vapour Density	No data available
Density	No data available
Solubility:	No data available
Partition Coefficient	No data available
Evaporation Rate	No data available

10. STABILITY AND REACTIVITY

Stability

Stable if kept in closed original containers under storage conditions as described in Section 7.



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Protect from moisture. This substance is stable if stored at 2~8°C. No dangerous decomposition material will form if handled as instructed.

Possibility of Hazardous Reactions

No data available

Conditions to Avoid

No data available

Incompatible Materials

Strong oxidizers

Hazardous Decomposition Products

No data available

11. TOXICOLOGICAL INFORMATION

Routes of Exposure

Inhalation

May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion

May be harmful if swallowed.

Skin

May be harmful if absorbed through skin. May cause skin irritation.

Eyes

May cause eye irritation.

Signs and Symptoms of Exposure

The most important known symptoms and effects are described in Section 2 and/or Section 11. To the best of our knowledge, the chemical, physical, and toxicological properties of this material have not been thoroughly investigated.

Acute toxicity

Oral LD50

Composition	Oral LD50
59122-46-2 Misoprostol	81 mg/Kg (Rat)
9004-65-3 Hydroxypropylmethylcellulose 2910	>2000 mg/Kg (Rat)

Inhalation LD50 No data available

Dermal LD50 No data available

Chronic toxicity

No data available

Carcinogenicity

Ingredient is not listed as carcinogenic by IARC, NTP, OSHA. No carcinogenic effects observed in tests with rats and mice.

Additional information:

Apart from ocular irritation and conjunctival or episcleral hyperemia, the ocular effects of this material administered at high doses are not known.

12. ECOLOGICAL AND DISPOSAL CONSIDERATIONS

Ecological Toxicity

No data available



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Persistence and Degradability

No data available

Bioaccumulative Potential

No data available

Mobility in Soil

No data available

Other Adverse Effects

No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods

Product

Product may be burned in an incinerator equipped with afterburner and scrubber. Excess and expired materials are to be offered to a licensed hazardous material disposal company. Ensure that all Federal and Local regulations regarding the disposal and destruction of this material are followed.

Contaminated Packaging

Dispose of as above.

Other Considerations

Product is not to be disposed of in sanitary sewers, storm sewers, or landfills.

14. TRANSPORT INFORMATION

UN Number

DOT (US): N/A IATA: N/A IMDG: N/A ADR/RID: N/A

UN proper Shipping Name

DOT (US): Not dangerous goods

IATA: Not dangerous goods

IMDG: Not dangerous goods

ARD/RID: Not dangerous goods

Transport Hazard Class(es)

DOT (US): N/A IATA: N/A IMDG: N/A ADR/RID: N/A

Packing Group

DOT (US): N/A IATA: N/A IMDG: N/A ADR/RID: N/A

Environmental Hazards

DOT (US): None IATA: None IMDG: None ADR/RID: None

Special Precautions for User

None

15. REGULATORY INFORMATION

This safety data sheet complies with the requirements of OSHA 1910.1200 (US) and EU Regulation EC No. 1907/2006 (European Union).



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16. OTHER INFORMATION

The information contained in this safety data sheet has been collected upon the present knowledge available with the utmost care but does not purport to be all inclusive and shall be used only as a guide. Insufficient data are available on the effect of this substance on human health. It is recommended for the user to ensure that this information is complete and sufficient for the specific use of this product.

Chirogate International Inc. shall not be held liable for any damage, of whatever nature, that might be caused by the use of this product and/or by the information presently submitted.