

SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Miconazole Nitrate Cream 4%
Synonym: 070

Manufacturer Name: Perrigo Company.
Address: 515 Eastern Avenue
Allegan, MI 49010 USA

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986 (U.S. calls)
+1 760-476-3962 Code 333304 (International calls)

Email Address: SDSRequest@perrigo.com

Recommended use: Human topical drug – vaginal antifungal
Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Skin Sensitization, Category 1

Label Elements:



Warning!

Hazard statement(s)

May cause an allergic skin reaction.

Precautionary statement(s)

Avoid breathing mists.
Contaminated clothing must not be allowed out of the workplace.
Wear protective gloves.
IF on Skin: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.
Dispose in accordance with local and national regulations

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Miconazole Nitrate	22832-87-7	4%
Water	7732-18-5	Proprietary
Potassium Hydroxide	1310-58-3	<0.1%
Benzoic Acid	65-85-0	<1%
Propylene Glycol	57-55-6	Proprietary
Polysorbate 60	9005-67-8	Proprietary
Cetyl Alcohol	36653-82-4	Proprietary
Stearyl Alcohol	112-92-5	Proprietary
Isopropyl Myristate	110-27-0	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation develops and persists, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye irritation. Ingestion may cause gastrointestinal distress and other adverse effects. May cause an allergic skin reaction in sensitized individuals.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is not normally required.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not flammable or combustible but may burn in a fire after the water has evaporated.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Miconazole Nitrate	Perrigo OEB2(100-1000 ug/m3)
Water	None Established
Potassium Hydroxide	2 mg/m3 Ceiling ACGIH TLV
Benzoic Acid	500 ug/m3 TWA Perrigo OEL
Propylene Glycol	10 mg/m3 TWA AHIA WEEL
Polysorbate 60	None Established
Cetyl Alcohol	None Established
Stearyl Alcohol	None Established
Isopropyl Myristate	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposures levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations.

Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): White to off-white cream

Odor: None

Odor threshold: Not applicable	pH: Not determined
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: None	Evaporation rate: Same as water
Flammability (solid, gas): Not applicable	VOC: Not determined
Flammable limits: LEL: None	UEL: None
Vapor pressure: Same as water	Vapor density: Same as water
Relative density: Not determined	Solubility(ies): Soluble
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Viscosity: Not determined

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract.

Ingestion: Swallowing may cause gastrointestinal distress with nausea and diarrhea and other adverse effects.

Skin contact: Minor irritation is possible. May cause an allergic skin reaction in sensitized individuals.

Eye contact: Contact may cause slight irritation with redness and tearing.

Chronic Effects: None known.

Sensitization: Components are skin sensitizers. Allergic reactions are possible in sensitized individuals.

Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity.

Reproductive Toxicity: Components are not known to cause reproductive or developmental toxicity. In animals miconazole has not shown teratogenic effects but is embryotoxic following high oral doses.

Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP or OSHA.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg

Miconazole Nitrate: Oral rat LD50 920 mg/kg

Propylene Glycol: LD50 oral rat 21-33.7 g/kg; LD50 dermal rabbit 20.8 g/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values: No data is available

Persistence and degradability: No data is available

Bioaccumulative potential: No data is available

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Refer to Section 2 for the OSHA Hazard Classification.

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 0 Instability = 0
HMIS Rating: Health = 1 Flammability = 0 Physical Hazard = 0

SDS Revision History: New SDS

Date of preparation: April 25, 2018

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

1. IDENTIFICATION

Product identifier: MICONAZOLE NITRATE VAGINAL CREAM 2%

Synonym: 214

Manufacturer Name: Perrigo Company.
Address: 515 Eastern Avenue
 Allegan, MI 49010 USA

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986 (U.S. calls)
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Email Address: SDSRequest@perrigo.com

Recommended use: Human topical drug – vaginal antifungal

Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

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Not hazardous	Skin Sensitization, Category 1

Label Elements:



Warning!

Hazard statement(s)
 May cause an allergic skin reaction.

Precautionary statement(s)

Avoid breathing mists.
 Contaminated clothing must not be allowed out of the workplace.
 Wear protective gloves.
 IF on Skin: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.
 Dispose in accordance with local and national regulations

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Miconazole Nitrate	22832-87-7	2%
Water	7732-18-5	Proprietary
Mineral Oil	8012-95-1	<10%
Polyoxyl -a with hydroxyl	9004-99-3	Proprietary
Fatty acids, C16-18, esters with ethylene glycol	91031-31-1	Proprietary

Glyceryl Stearate	31566-31-1	Proprietary
Apricot Kernel & Peg 6 esters	69071-70-1	Proprietary
Benzoic Acid	65-85-0	<1%
Ethylene Glycol	107-21-1	<0.1%
Butylated Hydroxyaisole	25013-16-5	<0.01%

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation develops and persists, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye irritation. Ingestion may cause gastrointestinal distress and other adverse effects. May cause an allergic skin reaction in sensitized individuals.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is not normally required.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not flammable or combustible but may burn in a fire after the water has evaporated.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Were appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Exposure guidelines:**

Miconazole Nitrate	Perrigo OEB2(100-1000 ug/m3)
Water	None Established
Mineral Oil	5 mg/m3 (inhalable) TWA ACGIH TLV 5 mg/m3 TWA OSHA PEL
Polyoxyl -a with hydroxyl	None Established
Fatty acids, C16-18, esters with ethylene glycol	None Established
Glyceryl Stearate	None Established
Apricot Kernel & Peg 6 esters	None Established
Benzoic Acid	500 ug/m3 TWA Perrigo OEL
Ethylene Glycol	100 mg/m3 Ceiling ACGIH TLV
Butylated Hydroxyaisole	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposures levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations.

Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): White cream

Odor: Slight odor of alcohol

Odor threshold: Not applicable	pH: Not determined
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: None	Evaporation rate: Same as water
Flammability (solid, gas): Not applicable	VOC: Not determined
Flammable limits: LEL: None	UEL: None
Vapor pressure: Same as water	Vapor density: Same as water
Relative density: Not determined	Solubility(ies): Soluble
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Viscosity: Not determined

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon and nitrogen oxides.

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Chronic Effects: None known.

Sensitization: Components are skin sensitizers. Allergic reactions are possible in sensitized individuals.

Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity.

Reproductive Toxicity: Components are not known to cause reproductive or developmental toxicity. In animals miconazole has not shown teratogenic effects but is embryotoxic following high oral doses.

Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP or OSHA.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg

Miconazole Nitrate: Oral rat LD50 920 mg/kg

Mineral Oil: LD50 oral rat >5000 mg/kg; LD50 dermal rabbit >2000 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values: No data is available

Persistence and degradability: No data is available

Bioaccumulative potential: No data is available

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
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Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Acute health

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

Canadian WHMIS Classification: Drugs are exempt from WHMIS

This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 0 Instability = 0
HMIS Rating: Health = 1 Flammability = 0 Physical Hazard = 0

SDS Revision History: New SDS

Date of preparation: July 25, 2015

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