

Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • Ertaczo® (sertaconazole nitrate) cream, 2%
- Product Code** • 301875115609; NDC 00187-5115-60
- Product Description** • Prescription pharmaceutical product.

Relevant identified uses of the substance or mixture and uses advised against

- Recommended use** • Finished Pharmaceutical Product; ERTACZO® (sertaconazole nitrate) cream, 2%, is indicated for the topical treatment of interdigital tinea pedis.
- Restrictions on use** • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

- Manufacturer** • Valeant Pharmaceuticals North America, LLC

Bridgewater, NJ 08807
United States
valeant.com

- Telephone (General)** • 1-800-321-4576

Emergency telephone number

- Manufacturer** • 1-800-535-5053 - US - Infotrac
- Manufacturer** • +1 352-323-3500 - International - Infotrac

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 consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

- UN GHS** • Skin Irritation 2
Eye Irritation 2A

Label elements

UN GHS

WARNING



- Hazard statements** • Causes skin irritation
Causes serious eye irritation

Precautionary statements

Prevention ● Wash thoroughly after handling.
Wear protective gloves/protective clothing/eye protection/face protection.

Response ● IF ON SKIN: Wash with plenty of soap and water.
If skin irritation occurs: Get medical advice/attention.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
Take off contaminated clothing and wash before reuse.

Storage/Disposal ● Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.
Keep tightly closed. Store at room temperature 20-25°C (68-77°F), to maintain product integrity. Use before date marked on carton and/or container.

Other hazards

UN GHS

- No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Glyceryl isostearate	CAS:66085-00-5 EINECS:266-124-4	1% TO 5%	UN GHS: NDA
Methylparaben	CAS:99-76-3 EINECS:202-785-7	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Mineral oil, light	CAS:8012-95-1 EINECS:232-384-2	5% TO 10%	UN GHS: NDA
Pegoxol-7 stearate	CAS:9004-99-3	15% TO 25%	UN GHS: NDA
Polyoxyethylened and glycolized saturated glycerides	NDA	5% TO 10%	UN GHS: NDA
Sertaconazole nitrate	CAS:99592-39-9	2%	UN GHS: NDA
Sorbic acid	CAS:110-44-1 EINECS:203-768-7	< 1%	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	> 60%	UN GHS: Classification criteria not met

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

Section 4: First-Aid Measures

Description of first aid measures

- Inhalation**
- Normal use of this product does not pose an inhalation hazard. However, should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.
- Skin**
- Wash skin with soap and water. If skin irritation occurs: Get medical advice/attention. Wash clothing separately before reuse.
- Eye**
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
- Ingestion**
- If swallowed, wash out mouth with water provided person is conscious. Seek medical attention.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

- Notes to Physician**
- Reported cutaneous adverse events included contact dermatitis, dry skin, burning skin, and skin tenderness.

Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Additional details are available on the product package insert or the Physicians Desk Reference.

Section 5: Fire-Fighting Measures

Extinguishing media

- Suitable Extinguishing Media**
- SMALL FIRES: Dry chemical, CO₂, water spray or regular foam.
LARGE FIRE: Water spray, fog or regular foam.

- Unsuitable Extinguishing Media**
- No data available

- Firefighting Procedures**
- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Special hazards arising from the substance or mixture

- Unusual Fire and Explosion Hazards**
- None known - product is not flammable or combustible.

- Hazardous Combustion Products**
- No data available

Advice for firefighters

- Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- Personal Precautions**
- Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Evacuate immediate area. Ventilate enclosed areas.
- Emergency Procedures**
- Keep unauthorized personnel away. For bulk material spills: Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not

reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Ventilate closed spaces before entering.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

Containment/Clean-up Measures

- Isolate hazard area. Prevent from entering drains and sewers. Cover with vermiculite or other suitable inert material, pick up and place in closed containers. Transport outdoors and hold for waste disposal. Ventilate area and wash spill site after material pickup is complete. Refer to Section 13 for appropriate disposal procedures.

Reference to other sections

- Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7 - Handling and Storage

Precautions for safe handling

Handling

- Use only in well ventilated areas (preferably in a chemical fume hood). Do not breathe dusts, vapors or mists. Do not get in eyes, on skin, or on clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Use good safety and industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Storage

- Keep tightly closed. Store at controlled room temperature 20-25°C/68-77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines					
	Result	ACGIH	Canada Quebec	NIOSH	OSHA
Mineral oil, light (8012-95-1)	STELs	Not established	10 mg/m3 STEV (mist)	10 mg/m3 STEL	Not established
	TWAs	5 mg/m3 TWA (excluding metal working fluids, highly & severely refined, inhalable fraction)	5 mg/m3 TWAEV (mist)	5 mg/m3 TWA	5 mg/m3 TWA

Exposure Control Notations

ACGIH

•Mineral oil, light (8012-95-1): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (highly and severely refined); A2 - Suspected Human Carcinogen (poorly and mildly refined))

Exposure controls

Engineering

Measures/Controls

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

Personal Protective Equipment

Pictograms

- 

Respiratory

- Where risk assessment shows that air-purifying respirators are appropriate, a NIOSH

(US) or CEN (EU) -certified air-purifying respirator equipped with HEPA and organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. Not required during normal clinical use.

Hands

- Wear protective gloves .

Skin/Body

- Wear protective gloves/protective clothing/eye protection/face protection. Not required during normal clinical use.

General Industrial Hygiene Considerations

- Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke during work. Avoid contact with skin, eyes or clothing. Wash thoroughly after handling.

Environmental Exposure Controls

- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid Cream	Appearance/Description	White or slightly yellow cream with a fluid consistency.
Color	White to slightly yellow.	Odor	No odor.
Odor Threshold	Not relevant		
General Properties			
Boiling Point	No data available	Melting Point	No data available
Decomposition Temperature	No data available	pH	3
Specific Gravity/Relative Density	= 0.95	Water Solubility	Soluble
Viscosity	Not relevant		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and humidities.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- This product is generally compatible with other common materials in a medical facility.

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Sertaconazole nitrate (2%)	99592-39-9	Acute Toxicity: Intraperitoneal-Mouse LD50 • 8000 mg/kg
Pegoxol-7 stearate (15% TO 25%)	9004-99-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 53 mL/kg; Irritation: Skin-Rabbit • 500 µL 24 Hour(s) • Severe irritation; Skin-Rabbit • 500 µL 24 Hour(s) • Moderate irritation
Methylparaben (< 1%)	99-76-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2100 mg/kg
Sorbic acid (< 1%)	110-44-1	Acute Toxicity: Ingestion/Oral-Rat LD50 • 7360 mg/kg
Mineral oil, light (5% TO 10%)	8012-95-1	Acute Toxicity: Ingestion/Oral-Rat LD50 • >24 g/kg; Gastrointestinal:Hypermotility, diarrhea

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Skin Irritation 2
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Eye Irritation 2A

Potential Health Effects

Inhalation

- Acute (Immediate)**
- May mildly irritate the respiratory tract. Symptoms may include coughing and congestion.
- Chronic (Delayed)**
- No data available

Skin

- Acute (Immediate)**
- May cause irritation. These reported cutaneous adverse events included contact dermatitis, dry skin, burning skin, and skin tenderness. Other possible cutaneous adverse events: erythema, pruritus, vesiculation, desquamation, and hyperpigmentation.
- Chronic (Delayed)**
- Repeated and prolonged exposure may cause sensitization. Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Eye

- Acute (Immediate)** ● Causes serious eye irritation.
- Chronic (Delayed)** ● No data available

Ingestion

- Acute (Immediate)** ● Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.
- Chronic (Delayed)** ● No data available

Section 12 - Ecological Information**Toxicity**

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects**Section 13 - Disposal Considerations****Waste treatment methods**

- Product waste** ● Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.
- Packaging waste** ● Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	NDA	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

- Special precautions for user** ● No data available

- Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** ● No data available

Section 15 - Regulatory Information**Safety, health and environmental regulations/legislation specific for the substance or mixture**

SARA Hazard Classifications • No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Sertaconazole nitrate	99592-39-9	No	No	No
Methylparaben	99-76-3	Yes	Yes	Yes
Pegoxol-7 stearate	9004-99-3	Yes	No	Yes
Glyceryl isostearate	66085-00-5	Yes	Yes	Yes
Mineral oil, light	8012-95-1	Yes	Yes	Yes
Sorbic acid	110-44-1	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada**Labor****Canada - WHMIS - Classifications of Substances**

• Methylparaben	99-76-3	Not Listed
• Sorbic acid	110-44-1	Uncontrolled product according to WHMIS classification criteria
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Sertaconazole nitrate	99592-39-9	Not Listed
• Pegoxol-7 stearate	9004-99-3	Uncontrolled product according to WHMIS classification criteria
• Glyceryl isostearate	66085-00-5	Not Listed
• Mineral oil, light	8012-95-1	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Methylparaben	99-76-3	Not Listed
• Sorbic acid	110-44-1	1 %
• Water	7732-18-5	Not Listed
• Sertaconazole nitrate	99592-39-9	Not Listed
• Pegoxol-7 stearate	9004-99-3	1 %
• Glyceryl isostearate	66085-00-5	Not Listed
• Mineral oil, light	8012-95-1	1 %

United States**Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Methylparaben	99-76-3	Not Listed
• Sorbic acid	110-44-1	Not Listed
• Water	7732-18-5	Not Listed
• Sertaconazole nitrate	99592-39-9	Not Listed
• Pegoxol-7 stearate	9004-99-3	Not Listed
• Glyceryl isostearate	66085-00-5	Not Listed
• Mineral oil, light	8012-95-1	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Methylparaben	99-76-3	Not Listed
• Sorbic acid	110-44-1	Not Listed
• Water	7732-18-5	Not Listed
• Sertaconazole nitrate	99592-39-9	Not Listed
• Pegoxol-7 stearate	9004-99-3	Not Listed
• Glyceryl isostearate	66085-00-5	Not Listed
• Mineral oil, light	8012-95-1	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Methylparaben	99-76-3	Not Listed
• Sorbic acid	110-44-1	Not Listed
• Water	7732-18-5	Not Listed
• Sertaconazole nitrate	99592-39-9	Not Listed
• Pegoxol-7 stearate	9004-99-3	Not Listed
• Glyceryl isostearate	66085-00-5	Not Listed
• Mineral oil, light	8012-95-1	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Methylparaben	99-76-3	Not Listed
• Sorbic acid	110-44-1	Not Listed
• Water	7732-18-5	Not Listed
• Sertaconazole nitrate	99592-39-9	Not Listed
• Pegoxol-7 stearate	9004-99-3	Not Listed
• Glyceryl isostearate	66085-00-5	Not Listed
• Mineral oil, light	8012-95-1	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Methylparaben	99-76-3	Not Listed
• Sorbic acid	110-44-1	Not Listed
• Water	7732-18-5	Not Listed
• Sertaconazole nitrate	99592-39-9	Not Listed
• Pegoxol-7 stearate	9004-99-3	Not Listed
• Glyceryl isostearate	66085-00-5	Not Listed
• Mineral oil, light	8012-95-1	Not Listed

Section 16 - Other Information**Last Revision Date**

- 11/May/2015

Preparation Date

- 11/May/2015

Disclaimer/Statement of Liability

- The above information and recommendations contained in the Safety Data Sheet have been compiled from sources believed to be accurate and reliable and to represent the most reasonable current opinion on the subject as of the date the SDS was prepared. No warranty, guaranty, or representation is made as to the correctness or sufficiency of the information. Such data are offered solely for consideration, investigation, and verification but do not purport to be all inclusive and should be used only as a guide. The user of this product must decide what safety measures are necessary to safely use this product, either alone or in combination with other products, and determine its environmental regulatory compliance obligations under any applicable federal or state laws.

