Schering-Plough

SAFETY DATA SHEET

This SDS was created in accordance with Regulation EC 1907/2006 and all amendments. Schering-Plough urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

PRODUCT IDENTIFIER

SDS NAME: **BUTENAFINE HYDROCHLORIDE CREAMS**

SYNONYM(S): Butenafine Hydrochloride Creams
Lotrimin Ultra, Athlete's Foot Cream
Lotrimin Ultra, Jock Itch Cream
Butenafine Hydrochloride Cream 1%
Tinactin Once-A-Day Cream

SDS Number: SP001004

REACH REGISTRATION NUMBER Not available

RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

IDENTIFIED USE(S): Consumer Product

USE(S) ADVISED AGAINST: None known.

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

EU SUPPLIER/MANUFACTURER: Schering-Plough HealthCare Products, Inc.
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Memphis, TN 38151

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EMERGENCY NUMBER(S): +1 (908) 423-6000 (24/7/365) English Only

SECTION 2. HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to EC Directive 1272/2008:
Based on available data, this mixture does not meet the criteria to be classified as hazardous according to EC DIrective 1272/2008.

Classification according to EC Directives 67/548/EEC (substances) or 1999/45/EC (mixtures):
Based on available data, this preparation does not meet the criteria to be classified as hazardous according to EC DIrective 1999/45/EC.

COLOR: White
FORM: Cream
ODOR: Odor unknown

LABEL ELEMENTS

Based on available data, this mixture does not meet the criteria to be classified as hazardous in accordance with Directive 1272/2008.

OTHER HAZARDS

Health-Related Hazards:

Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.

LISTED CARCINOGENS

INGREDIENT	CAS NUMBER	IARC	EU
White Petrolatum	8009-03-8		2

The EU Directive 90/394 (Annex 1) lists petrolatum as a carcinogen; however, this classification is based on less refined grades of petrolatum (yellow, amber or brown), used industrially. The petrolatum used in this product is white petrolatum, which is a highly refined grade used in pharmacy and cosmetics.

INGREDIENT	REACH - Carcinogens	REACH - Mutagens	REACH - Toxic to Reproduction
White Petrolatum	1B		

Environmental-Related Hazards:

This substance has not been fully tested to meet the criteria for listing as a PBT or a vPvB.

Other Hazards:

No other information known.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

SUBSTANCE

CHEMICAL FORMULA: Mixture.

The formulations for these products are proprietary information. These formulations have the same hazardous profile; however, the presence of hazardous ingredients may vary by formulation. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	EC NUMBER	REACH REGISTRATION NUMBER	EU CLASSIFICATION	GHS CLASSIFICATION	PERCENT	REASON FOR LISTING
Butenafine Hydrochloride	101827-46-7	Not available	Not available	Xn;R21	Acute Tox. 4 (H312)	1	Active Ingredient Classified
Glycerin	56-81-5	200-289-5	x	Not Classified	Not Classified	< 10	Community workplace exposure limit
Glyceryl Monostearate	31566-31-1	250-705-4	x			<10	Community workplace exposure limit
Cetyl Alcohol	36653-82-4	253-149-0	x	Xi;R38	Skin Irrit. 2 (H315)	<10	Classified

INGREDIENT	CAS NUMBER	EC NUMBER	REACH REGISTRATION NUMBER	EU CLASSIFICATION	GHS CLASSIFICATION	PERCENT	REASON FOR LISTING
White Petrolatum	8009-03-8	232-373-2	x	Carc.Cat.2; R45	Carc. 1B (H350)	< 10	Classified

The EU Directive 90/394 (Annex 1) lists petrolatum as a carcinogen; however, this classification is based on less refined grades of petrolatum (yellow, amber or brown), used industrially. The petrolatum used in this product is white petrolatum, which is a highly refined grade used in pharmacy and cosmetics.

Fields in the above table that do not contain data indicate that the substance(s) have not been listed or classified according to EU criteria.

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

See section 16 for definitions of risk phrases and GHS classifications.

SECTION 4. FIRST AID MEASURES

FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In keeping with good hygienic practices, wash exposed areas thoroughly with soap and water.

EYE CONTACT: As with any material contacting the eye, it is recommended to rinse eyes with water.

INGESTION: Rinse mouth with water. If symptoms develop, consult a physician.

FIRST AID RESPONDER PROTECTION: Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves with appropriate personal protective equipment. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. DO NOT use mouth-to-mouth method if victim ingested or inhaled the substance.

MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Although some ingredients used in the manufacture of this product are considered hazardous on an individual basis, the final formulation of this product is considered non-hazardous when used according to manufacturer's directions.

This product was shown to be a slight skin irritant in humans and a slight to moderate irritant in animals. Based on animal studies, this product may cause slight to moderate eye irritation. In clinical trials using a 1% butenafine cream formulation, contact dermatitis, redness, irritation and itching were occasionally reported.

INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

NOTE TO PHYSICIAN: In cases of overexposure treat supportively and symtomatically.

SECTION 5. FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO2), extinguishing powder or water spray.

UNSUITABLE EXTINGUISHING MEDIA:
None known.

SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

SPECIAL FIRE HAZARDS:
None known.

ADVICE FOR FIREFIGHTERS

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing and self-contained breathing apparatus (SCBA).

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

PERSONAL PRECAUTIONS:
Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

SPILL RESPONSE / CLEANUP:
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

HANDLING:
Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

CONDITIONS FOR SAFE STORAGE, INCLUDING ANY IMCOMPATIBILITIES

STORAGE:
Store in a cool, dry, well ventilated area.

SPECIFIC END USE(S)
Refer to Section 1 for identified use(s).

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

CONTROL PARAMETERS

EXPOSURE LIMIT VALUES:

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)
Glycerin	56-81-5	10 mg/m^3		
Glyceryl Monostearate	31566-31-1	10 mg/m^3		

INGREDIENT	CAS NUMBER	EU	Austria	Belgium	Denmark	France
Glycerin	56-81-5			TWA 10 mg/m^3		VME 10 mg/m^3
Glyceryl Monostearate	31566-31-1			TWA 10 mg/m^3		

INGREDIENT	CAS NUMBER	Germany	Ireland	Italy	Netherlands
Glycerin	56-81-5	MAK 50 mg/m^3 Peak 100 mg/m^3	TWA 10 mg/m^3		
Glyceryl Monostearate	31566-31-1		TWA 10 mg/m^3		

INGREDIENT	CAS NUMBER	Norway	Portugal	Spain	Switzerland	UK:
Glycerin	56-81-5		TWA 10 mg/m^3	VLA-ED 10 mg/m^3	STEL 100 mg/m^3 MAK 50 mg/m^3	STEL 30 mg/m^3 TWA 10 mg/m^3
Glyceryl Monostearate	31566-31-1		TWA 10 mg/m^3	VLA-ED 10 mg/m^3		

INGREDIENT	Greece	Poland	Hungary	Croatia	Turkey
Glycerin	TWA 10 mg/m^3	NDS 10 mg/m^3		TWA 10 mg/m^3	

EXPOSURE CONTROLS

The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Body Protection: None required for consumer use of this product.

In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

Skin Protection: None required for consumer use of this product.

Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.

Respiratory Protection: None required for consumer use of this product.

Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.

Eye Protection: None required for consumer use of this product.

Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

FORM: Cream
COLOR: White
ODOR: Odor unknown
ODOR THRESHOLD: Not determined
pH: 4.5-6.5 at 10% concentration
BOILING POINT / RANGE: Not determined
MELTING POINT / RANGE: Not determined
DECOMPOSITION TEMPERATURE: Not determined
VAPOR PRESSURE: Not determined

VAPOR DENSITY:	Not determined
SPECIFIC GRAVITY:	Not determined
SOLUBILITY:	
Water:	Dispersible
PARTITION COEFFICIENT (log Pow):	Not determined
VISCOSITY:	Not determined
EVAPORATION RATE:	Not determined
FLAMMABILITY DATA:	
Flash Point:	Not determined (liquids) or not applicable (solids).
Flammability (solid, gas):	Not determined
UEL:	Not determined
LEL:	Not determined
Autoignition Temperature:	Not determined

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under conditions specified in Section 7 of this SDS. No hazardous reactions known.

CONDITIONS AND MATERIALS TO AVOID:
None known.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
No dangerous decomposition is expected if used according to manufacturer's specifications.

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the formulated product unless indicated otherwise.

Although some ingredients used in the manufacture of this product are considered hazardous on an individual basis, the final formulation of this product is considered non-hazardous when used according to manufacturer's directions.

LIKELY ROUTES OF EXPOSURE:
Skin, eye, inhalation, and ingestion.

ACUTE TOXICITY DATA

INHALATION:
No data available.

ORAL:
Practically not toxic.

EYE:
Slight to moderate irritant.

SKIN:
Slight to moderate irritant.

ASPIRATION:
No data available.

DERMAL AND RESPIRATORY SENSITIZATION:
Not sensitizing.

ADDITIONAL INFORMATION:
Negative in phototoxicity and photosensitivity studies.

SUBCHRONIC / CHRONIC TOXICITY:
No data available.

REPEAT DOSE TOXICITY DATA

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Butenafine did not cause fertility or teratogenicity in animals given subcutaneous or topical doses at 5-12 times (25-50 mg/kg/day) the maximum recommeded human doses.

MUTAGENICITY / GENOTOXICITY:
Butenafine was not mutagenic in the Ames bacterial reverse mutation assay, in vitro chromosome aberration assay, or rat micronucleus assay.

CARCINOGENICITY:
This material or product has not been evaluated for carcinogenicity.

Classification according to EC Directive 1272/2008:
Based on available data, this mixture does not meet the criteria to be classified as hazardous according to EC DIrective 1272/2008..

Classification criteria have not been met for the following endpoints due to lack of data, inconclusive data, technical impossibility to obtain the data, or data which are conclusive although insufficient for classification (available information to support classification criteria is given in Section 4 or Section 11 of this data sheet):
Inhalation toxicity. Dermal toxicity. Eye damage or irritation. Oral toxicity. Skin sensitization. Skin corrosion or irritation. Respiratory sensitization. Mutagenicity. Carcinogenicity. Reproductive toxicity. Specific target organ toxicity (STOT) - Single Exposure. Specific target organ toxicity (STOT) - Repeated Exposure. Aspiration hazard.

See Section 4 for human health symptoms and effects.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

This product has not been tested for ecotoxicity.

PERSISTENCE AND DEGRADABILITY

Biodegradation Results: No data available.

BIOACCUMULATIVE POTENTIAL

Partition Coefficient (log Pow) Results: No data available.

MOBILITY IN SOIL

Soil Adsorption/Desorption Results: No data available.

PBT and vPvB ASSESSMENT

This substance has not been assessed.

OTHER ADVERSE EFFECTS

ENVIRONMENTAL FATE AND EFFECTS: No data available.

SECTION 13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT METHODS

MATERIAL WASTE:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15. REGULATORY INFORMATION

SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Germany, Water Endangering Classes (WGK)

INGREDIENT	Annex 1	Annex 2 - Water Hazard Classes	Annex 3
Butenafine Hydrochloride	Not listed.	Not listed.	Not listed.
Glycerin	Not listed.	116	Not listed.
Glyceryl Monostearate	Not listed.	690	Not listed.
Cetyl Alcohol	656	Not listed.	Not listed.
White Petrolatum	Not listed.	Not listed.	Not listed.

Ozone Depleting Substance(s)

INGREDIENT	Listing
Butenafine Hydrochloride	Not listed.
Glycerin	Not listed.
Glyceryl Monostearate	Not listed.
Cetyl Alcohol	Not listed.
White Petrolatum	Not listed.

Persistent Organic Pollutants

INGREDIENT	Listing
Butenafine Hydrochloride	Not listed.
Glycerin	Not listed.
Glyceryl Monostearate	Not listed.
Cetyl Alcohol	Not listed.
White Petrolatum	Not listed.

EU Import and Export Restrictions

INGREDIENT	Requires PIC Notification	Requires Export Notification	Export Ban
Butenafine Hydrochloride	Not listed.	Not listed.	Not listed.
Glycerin	Not listed.	Not listed.	Not listed.
Glyceryl Monostearate	Not listed.	Not listed.	Not listed.
Cetyl Alcohol	Not listed.	Not listed.	Not listed.
White Petrolatum	Not listed.	Not listed.	Not listed.

SEVESO II EU Directive

INGREDIENT	Listing
Butenafine Hydrochloride	Not listed.
Glycerin	Not listed.
Glyceryl Monostearate	Not listed.
Cetyl Alcohol	Not listed.
White Petrolatum	Not listed.

REACH

INGREDIENT	Subject to Authorization	Candidate List for Authorization	Potential Substances of High Concern	Restrictions
Butenafine Hydrochloride	Not listed.	Not listed.	Not listed.	Not listed.
Glycerin	Not listed.	Not listed.	Not listed.	Not listed.
Glyceryl Monostearate	Not listed.	Not listed.	Not listed.	Not listed.
Cetyl Alcohol	Not listed.	Not listed.	Not listed.	Not listed.
White Petrolatum	Not listed.	Not listed.	Not listed.	x

CHEMICAL SAFETY ASSESSMENT

A Chemical Safety Assessment has not been done.

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness 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).

DEPARTMENT ISSUING SDS:

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SUPERSEDES DATE: 05-Mar-2012

SIGNIFICANT CHANGES (EU SUBFORMAT): Synonyms

DEFINITIONS (referred to under Sections 2 and 3):

CLP Classifications: • Acute Tox. 4 (H312) - Harmful in contact with skin. • Skin Irrit. 2 (H315) - Causes skin irritation. • Carc. 1B (H350) - May cause cancer.	• Based on available data, this mixture does not meet the criteria to be classified as hazardous according to EC DIrective 1272/2008.
Risk Phrases:	• Based on available data, this preparation does not meet the criteria to be classified as hazardous according to EC DIrective 1999/45/EC. • R21 - Harmful in contact with skin. • R38 - Irritating to skin. • R45 - May cause cancer.

GLOSSARY:
IARC - International Agency for Research on Cancer, IARC Group 1 or 2A.
NTP - National Toxicology Program
ACGIH - American Conference of Governmental Industrial Hygienists
ADR - International Carriage of Dangerous Goods by Road
API - Active Pharmaceutical Ingredient
CAS - Chemical Abstract Service
CLP - Classification, Labeling and Packaging
DOT - Department of Transportation
EC - European Council
ETAC - Estimated Target Airborne Concentration
GHS - Globally Harmonized System
HEPA - High Efficiency Particulate Arresting
HHC - Health Hazard Category
HPA - Hypothalamic Pituitary Adrenal
IATA - International Air Transport Association
IMO - International Maritime Organization
IP - Intraperitoneal Injection
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%
LOEL - Lowest Observed Effect Level
NEL - No Effect Level
NOAEL - No Adverse Effect Level
NOEL - No Observe Effect Level
OEG - Occupational Exposure Guideline
PBT - Persistent BioaccumulativeToxic
PG - Packing Group
PIC - Prior Informed Consent
PPE - Personal Protective Equipment
REACH - Registration, Evaluation, Authorization and Restriction of Chemical Substances
RPE - Respiratory Protective Equipment
SCBA - Self Contained Breathing Apparatus
STOT - Specific Target Organ Toxicity
TSCA - Toxic Substances Control Act
TWA - Time Weighted Average
UN - United Nations
vPvB - Very Persistent andVery Bioaccumulative
WGK - Water Hazard Class (Germany)