



Evoclin (Clindamycin Phosphate) Foam

SAFETY DATA SHEET

North America GHS

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations & the Hazardous Products Regulation (February 11, 2015) & NORMA Oficial Mexicana NOM-018-STPS-2015

1. IDENTIFICATION

Product identifier

Product Name: Evoclin (Clindamycin Phosphate) Foam

Synonyms: Evoclin Foam; Evoclin Foam, 1%; Clindamycin Phosphate 1% Foam

Other means of identification

Other Information: No other information

Recommended use of the chemical and restrictions on use

Recommended Use: Pharmaceutical. Use only as directed. For external use only.

The intent of this safety data sheet (SDS) is to provide safety information for occupational handling of this product. This information may not be relevant for medical use of this product. Patients/ consumers should consult the package insert/ product label/ physician/ pharmacist for information regarding the usage of this product. For information on the ingredients used in this product, refer to the appropriate SDS for each ingredient.

Uses advised against: No information available.

Details of the supplier of the safety data sheet

Mylan Inc.

Robert J. Coury Global Center

1000 Mylan Blvd.

Canonsburg, PA 15317, USA

+1.724.514.1800

Contact e-mail:

SDScontact@mylan.com

Emergency telephone number

Emergency Telephone:

24 hr. Emergency Contact ChemTel

International: +1-813-248-0585

US & Canada: 1-800-255-3924

Mexico: 800-099-0731

2. HAZARDS IDENTIFICATION

Classification

Serious eye damage/eye irritation, Category 2A

Flammable aerosols Category 1

Label elements



Signal word:

Warning

Hazard statements:

H222 - Extremely flammable aerosol

H229 - Pressurized container: May burst if heated

H319 - Causes serious eye irritation

Precautionary Statements - Prevention:

Avoid breathing dust/fume/gas/mist/vapors/spray

Contaminated work clothing must not be allowed out of the workplace

Wear protective gloves/eye protection/face protection

Avoid release to the environment

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
Do not spray on an open flame or other ignition source

Eyes: 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

Skin: IF ON SKIN: Wash with plenty of water and soap
If skin irritation or rash occurs: Get medical advice/attention
Wash contaminated clothing before reuse

Precautionary Statements - Storage: Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F

Precautionary Statements - Disposal: Dispose of contents/container to an approved waste disposal plant
Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Other Hazards

No information available.

Unknown acute toxicity

No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS**Mixture**

Chemical name	CAS No	Weight-%	Hazard statements
Ethanol	64-17-5	50 - 60	H225 - Highly flammable liquid and vapor H319 - Causes serious eye irritation
Propane	74-98-6	<5	H220 - Extremely flammable gas H280 - Contains gas under pressure; may explode if heated
n-Butane	106-97-8	<5	H220 - Extremely flammable gas H280 - Contains gas under pressure; may explode if heated
Isobutane	75-28-5	<5	H220 - Extremely flammable gas H280 - Contains gas under pressure; may explode if heated
Clindamycin Phosphate	24729-96-2	1.0	H302 - Harmful if swallowed H317 - May cause an allergic skin reaction H319 - Causes serious eye irritation

4. FIRST AID MEASURES**Description of first aid measures**

Overdose: Refer to information on package labeling and packaging. In case of overdose, get medical help or contact a Poison Control Center right away.

General advice: Show this safety data sheet to the doctor in attendance.

Inhalation: IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur.

Skin contact: Wash with soap and water. In the case of skin irritation or allergic reactions see a physician.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.

Ingestion: Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider: Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms: Itching. Rashes. Hives. Burning sensation.

Indication of any immediate medical attention and special treatment needed

May cause sensitization in susceptible persons. Treat symptomatically.

5. FIRE-FIGHTING MEASURES**Extinguishing media**

Suitable Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical

Fire hazard: Flammable aerosol.

Explosive hazard: Contents under pressure.

Reactivity: Hazardous reactions will not occur under normal conditions.

Hazardous combustion products: Carbon oxides. Nitrogen oxides. Hydrocarbons.

Advice for firefighters

Precautionary measures in case of fire: Standard procedure for chemical fires.

Firefighting instructions: Use water spray or fog; do not use straight streams.

Protection of Firefighters: Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Other Information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES**Personal precautions, protective equipment and emergency procedures**

Personal precautions: Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

For non-emergency personnel

Personal Protective Equipment: Use personal protective equipment as required.

Emergency procedures: Evacuate personnel to safe areas.

For emergency responders

Personal Protective Equipment: Use personal protective equipment as required.

Emergency procedures: Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.

Other Information: Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Do not flush into surface water or sanitary sewer system. Should not be released into the environment. See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment: Prevent further leakage or spillage if safe to do so.

Methods for cleaning up: Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills: Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.

Prevention of secondary hazards: Clean contaminated objects and areas thoroughly observing environmental regulations.

Reference to other sections

See section 8 for more information. See section 13 for more information.

7. HANDLING AND STORAGE**Precautions for safe handling**

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Advice on safe handling: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Storage Conditions: Store in a cool, dry area away from potential sources of heat, open flames, sunlight or other chemicals. Keep out of the reach of children. Keep at temperatures between 20 and 25 °C (68 and 77 °F).

Specific end use(s): Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Control parameters**

Exposure Limits: No information available

Exposure controls

Appropriate engineering controls: Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Individual protection measures, such as personal protective equipment

Hand protection: Wear suitable gloves.

Eye/face protection: Wear safety glasses with side shields (or goggles). If splashes are likely to occur, wear safety glasses with side-shields.

Skin and body protection: Skin sensitizer. Avoid contact with skin. Wear suitable protective clothing. Wash thoroughly after handling.

Respiratory protection: Use appropriate respiratory protection.

General hygiene considerations: Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.

9. PHYSICAL AND CHEMICAL PROPERTIES**Information on basic physical and chemical properties**

Physical state: Liquid; Aerosol

Appearance: Foam

Color:	white
Odor:	No data available
Odor threshold:	No data available
pH:	No data available
Melting point / freezing point:	No data available
Boiling point / boiling range:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability (solid, gas):	No data available
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Relative density:	No data available
Water solubility:	No data available
Solubility in other solvents:	No data available
Partition coefficient:	No data available
Autoignition temperature:	No data available
Decomposition temperature:	No data available
Kinematic viscosity:	No data available
Dynamic viscosity:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available
<u>Other Information</u>	
VOC Content (%):	55 - 60% estimated

10. STABILITY AND REACTIVITY

Reactivity

Hazardous reactions will not occur under normal conditions.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

Extremes of temperature and direct sunlight.

Incompatible materials

Strong oxidizing agents, strong acids, and strong bases.

Hazardous decomposition products

Decomposition will not occur under normal conditions.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Information on likely routes of exposure

Inhalation: Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.

Ingestion: Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Eye contact: Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.

Skin contact: May cause sensitization by skin contact. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms: Itching. Rashes. Hives. Burning sensation.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation: May cause skin irritation.

Serious eye damage/eye irritation: Classification based on data available for ingredients. Irritating to eyes.

Respiratory or skin sensitization: May cause sensitization by skin contact.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT - single exposure: Based on available data, the classification criteria are not met.

STOT - repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Numerical measures of toxicity**Acute toxicity:** No information available**12. ECOLOGICAL INFORMATION****Ecotoxicity**

No information available.

Persistence and degradability

No information available.

Bioaccumulation

No information available.

Mobility

No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS**Waste treatment methods**

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

California Hazardous Waste Status

This product contains one or more substances that are listed with the State of California as a hazardous waste.

14. TRANSPORT INFORMATION

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

In accordance with DOT / ICAO / IATA / TDG**UN Number**

UN 1950

UN proper shipping name

Aerosols, flammable, n.o.s. (Ethanol, Propane)

Transport hazard class(es)

Hazard Class: 2.1

**Packing group**

Not applicable

Environmental hazards

No

Special precautions for user

No information available

Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

Special Provisions

Shipper, please take note that in addition to limited and/or excepted quantity exemptions, the following Special Provisions may apply to this product.

US DOT: DOT - ORM-D**TDG:** TDG - 80; TDG - 107**IMDG:** IMDG - 63; IMDG - 190; IMDG - 277; IMDG - 327; IMDG - 344; IMDG - 381; IMDG - 959**IATA:** IATA - A145; IATA - A153**15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture****International Regulations****Ozone-depleting substances (ODS):** Not applicable**Persistent Organic Pollutants:** Not applicable**The Rotterdam Convention:** Not applicable

US Federal Regulations

SARA 313: Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

CWA (Clean Water Act)

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

U.S. State Right-to-Know Regulations**US State Regulations:**

Chemical name	New Jersey	Massachusetts	Pennsylvania
Ethanol 64-17-5	X	X	X
Propane 74-98-6	X	X	X
n-Butane 106-97-8	X	X	X
Propylene Glycol 57-55-6	X	-	X
Isobutane 75-28-5	X	X	X

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

16. OTHER INFORMATION

Revision Date: 10-December-2019

Other Information: This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

Key or legend to abbreviations and acronyms used in the safety data sheet:**Legend, Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA: TWA (time-weighted average)

STEL: STEL (Short Term Exposure Limit)

Party responsible for the preparation of this document:

Mylan Global Environmental, Health, and Safety Department - Occupational Toxicology

Phone number: +1 304-559-2595

This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product.

Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.