Section 1. Identification

1.1 Substance Name: Mupirocin Cream USP, 2%

1.2 Chemical Name: (E)-(2S,3R,4R,5S)-5-[(2S,3S,4S,5S)-2,3-Epoxy-5-hydroxy-4-methylhexyl]tetrahydro-3,4-dihydroxy-β-methyl-2H-pyran-2-crotonic Acid, Ester with 9-Hydroxynonanoic Acid

1.3 Relevant identified uses of the substance or mixture and uses advised against: Antibiotic applied topically as a 2% ointment for the treatment of various bacterial skin infections. Also used for eradication of the nasal carriage of epidemic methicillin-resistant Staphylococcus aureus. Inhibits bacterial protein synthesis by binding to isolecyl transfer RNA synthetase. Effective against most strains of staphylococci and streptococci and against some gram-negative bacteria. [~Antibacterial ~]

1.4 Company Identification: Glenmark Pharmaceuticals Inc., USA
750 Corporate Drive

Mahwah, NJ 07430

1.6 Emergency Contact details: (201) 684-8000

Section 2. Hazard Identification

2.1 Classification of the substance or mixture

Classification according to Regulation GHS

Chemwatch Hazard Ratings

		Min	Max
Flammability	**1**	■	
Toxicity	**0**		

Body Contact **2** [redacted]

Reactivity **1** [redacted]

Chronic **2** [redacted]

0 = Minimum
1 = Low
2 = Moderate
3 = High
4 = Extreme
Relevant risk statements are found in section 2

2.2 Label elements: Not Known

2.3 Other hazards:

May produce skin discomfort*.
Cumulative effects may result following exposure*.

Section 3- Composition/Information on Ingredients

3.1 Substances

CHEMICAL NAME	CAS #	% w/w
Mupirocin	12650-69-0	2
ingredients determined not to be hazardous [Mfr]	-	98

Formula: C26-H44-O9

Section 4. First aid Measures

4.1 Inhalation:

- If fumes, aerosols or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary.

4.2 Skin: If skin contact occurs:

- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

4.3 Eyes: If this product comes in contact with eyes:

- Wash out immediately with water.
- If irritation continues, seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

4.4 Ingestion:

- Immediately give a glass of water.
- First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

4.5 Most important symptoms and effects, both acute and delayed

Treat symptomatically.

Section 5. Fire-fighting Measures

5.1 General Information:

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use water delivered as a fine spray to control fire and cool adjacent area.

5.2 Extinguishing Media:

- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

5.3 Fire/Explosion Hazard:

- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
- Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions).
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.

5.4 Fire Incompatibility: Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result

5.4 NFPA Rating: Health=1, Flammability=1 and Stability=0

Section 6. Accidental Release Measures

6.1 General Information: Personal Protective Equipment advice is contained in Section 8 of the SDS.

6.2 Minor Spills:

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.

6.3 Major Spills: Moderate hazard.

- CAUTION: Advise personnel in area.
- Alert Emergency Services and tell them location and nature of hazard.
- Control personal contact by wearing protective clothing.

Section 7. Handling and Storage

7.1 Handling:

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.

7.2 Storage:

- Store in original containers.
- Keep containers securely sealed.

- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.

7.3 Suitable Container:

- Glass container is suitable for laboratory quantities
- Polyethylene or polypropylene container.
- Check all containers are clearly labeled and free from leaks.

7.4 Storage incompatibility: Avoid reaction with oxidizing agents

Section 8. Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits (OEL):

Ingredient Data

Not Available

Emergency Limits

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
Mupirocin	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
Mupirocin	Not Available	Not Available

Material Data

It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace.

At this time no TLV has been established, even though this material may produce adverse health effects (as evidenced in animal experiments or clinical experience). Airborne concentrations must be maintained as low as is practically possible and occupational exposure must be kept to a minimum.

Note: The ACGIH occupational exposure standard for Particles Not Otherwise Specified (P.N.O.S) does NOT apply.

8.2 Exposure controls:

Appropriate engineering controls	Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg.
Personal protection	 

	 
Eye and face protection	When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs: Chemical goggles. Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.
Skin protection	See Hand protection below
Hands/feet protection	The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice. Suitability and durability of glove type is dependent on usage.
Body protection	See Other protection below
Other protection	For quantities up to 500 grams a laboratory coat may be suitable. For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and

	cuffs. For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
Thermal hazards	Not Available

Recommended material(s)
Glove Selection Index

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the **computer-generated** selection:

MUPIROCIN Not Available

Material **CPI**

* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

Note: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

Respiratory protection
Not Available

Required Minimum Protection Factor	**Half-Face Respirator**	**Full-Face Respirator**	**Powered Air Respirator**

up to 10 x ES	P1	-	PAPR-P1
	Air-line*	-	-
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

Section 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	:	Cream
Appearance	:	white to off-white Cream
Colour	:	white to off-white
pH Value	:	Not Known
Vapor Pressure	:	Not Known
Vapor Density	:	Not Known
Evaporation Rate	:	Not Known
Other information		
Flash point	:	Not Known
Molecular Weight	:	Not Known
Melting point/range	:	Not Known

Boiling point/boiling range	:	Not Known
Density	:	Not Known
Viscosity	:	Not Known
Water solubility	:	Partly Miscible
Solubility in other solvents	:	Not Known
Minimum ignition energy (MIE)	:	Not Known
Minimum ignition temperature (MIT)	:	Not Known
Layer ignition temperature (LIT)	:	Not Known
Flammability/explosivity	:	Not Known
Reactivity/exotherms	:	Not Known
Electrostatic nature	:	Not Known
Highly dusty material	:	Not Known
Any other properties which cause handling or processing difficulties	:	Not Known
Average PSD (particle size distribution (micron)	:	Not Known

9.2 Other Information

Not Known

Section 10. Stability and Reactivity

10.1 Reactivity: Product is considered stable

10.2 Chemical stability: Product is considered stable

10.3 Conditions to Avoid: Avoid reaction with oxidizing agents

10.4 Incompatibilities with Other Materials: Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result

10.5 Hazardous Decomposition Products:
Combustion: If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides). Hydrolysis: None known.

10.6 Hazardous Polymerization: Will not occur

Section 11. Toxicological Information

11.1 Information on toxicological effects

Inhaled	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.
Ingestion	Although ingestion is not thought to produce harmful effects (as classified under EC Directives), the material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.
Skin Contact	Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions. Limited evidence exists, or practical experience predicts, that the material either

	produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterized by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis.
Eye	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.
Chronic	Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems. Long term exposure to high dust concentrations may cause changes in lung function (i.e. pneumoconiosis) caused by particles less than 0.5 micron penetrating and remaining in the lung. A prime symptom is breathlessness. Lung shadows show on X-ray.
mupirocin	**TOXICITY** / **IRRITATION** Oral (rat) LD50: 5000 mg/kg[2] / Not Available
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

Section 12. Ecological Information

12.1 Toxicity:

Not Available

Ingredient	Endpoint	Test Duration	Effect	Value	Species	BCF
Mupirocin	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available

12.2 Persistence and degradability:

Ingredient	Persistence: Water/Soil	Persistence: Air
Mupirocin	LOW	LOW

12.3 Bioaccumulative potential:

Ingredient	Bioaccumulation
Mupirocin	LOW (LogKOW = 2.9588)

12.4 Mobility in soil:

Ingredient	Mobility
Mupirocin	LOW (KOC = 10)

12.5 Other: Not Known

Section 13. Disposal Considerations

13.1 Waste treatment methods

Product / Packaging disposal	Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked. A Hierarchy of Controls seems to be common - the user should investigate: Reduction Reuse Recycling Disposal (if all else fails) This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use.

Section 14. Transport Information

14. 1 Special precautions for user:

Labels Required

Marine Pollutant	NO

Land transport (UN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS
Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS
Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS
Transport in bulk according to Annex II of MARPOL 73 / 78 and the IBC code

Source	Ingredient	Pollution Category
IMO MARPOL 73/78 (Annex II) - List of Noxious Liquid Substances Carried in Bulk	Mupirocin	Y

Section 15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

MUPIROCIN(12650-69-0) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Not Applicable

National Inventory	Status
Australia - AICS	N (mupirocin)
Canada - DSL	N (mupirocin)
Canada - NDSL	N (mupirocin)
China - IECSC	N (mupirocin)
Europe - EINEC / ELINCS / NLP	N (mupirocin)
Japan - ENCS	N (mupirocin)
Korea - KECI	N (mupirocin)
New Zealand - NZIoC	Y
Philippines - PICCS	N (mupirocin)
USA - TSCA	N (mupirocin)
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

Section 16. Additional Information

Disclaimer:
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Compiled By (R & D)	Approved by (EHS Head)
06/10/15	07/10/2015
Signature /Date	Signature /Date