

SAFETY DATA SHEET

Product Name : Griseofulvin 125mg / 5ml Oral Suspension USP	
Date of Issue : 16.03.2017	Revision No. : 01

1 IDENTIFICATION

This section identifies the chemical on the SDS as well as the recommended uses. It also provides the essential contact information of the supplier.

- Product Name** : Griseofulvin 125mg / 5ml Oral Suspension USP
- Synonyms (if any)** : NA
- Company Name** : Cipla Ltd.,
- Company Address** : Plot No. 9 & 10, Pharma zone, Phase II, Sector III, Indore Special Economic zone, Pithampur, Dist: Dhar, Madhya Pradesh-454775
- Telephone** : +91 2225712463 **Fax** : +91 227913111
- E-mail** : Dsafe@cipla.com **Web site** : www.cipla.com
- Emergency Contact** : +91 2225712463
- Recommended Use / Restrictions on Use (if any):** NA

2 HAZARD(S) IDENTIFICATION


This section identifies the hazards of the chemical presented on the SDS and the appropriate warning information associated with those hazards.

- Classification as per EC - Physical** : This product is not hazardous
- Health** : Product may be slightly harmful if overdose
- Environmental** : Information Not Available

Label in accordance with EC - Information not available

Signal Word - Product is Non-Hazardous

Hazard Statement(s) - Product is Non-Hazardous


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Pictograms –



Precautionary Statement(s) –

Keep away from Direct sunlight,

Description of any hazards not otherwise classified – Information not available

% of the mixture consisting of ingredient(s) with unknown acute toxicity - Information not available

3 COMPOSITION / INFORMATION ON INGREDIENTS


This section identifies the ingredient(s) contained in the product indicated on the SDS, including impurities and stabilizing additives. This section includes information on substances, mixtures, and all chemicals where a trade secret is claimed.

Chemical name : Griseofulvin
Common Name / Synonyms :
Molecular Formula : C17-H17-Cl-O6 (of API)
Molecular Weight : 352.77 g / mole (of API)
CAS No. : 126-07-8 (of API) **UN No.** : Information not Available **EC No.** : Information not Available

Classified Impurities and stabilizing additives: Information not Available

Mixture (Ingredient Name, Concentration):

- Griseofulvin: 2.5%
- Sucrose (Baker's special granulated): 45%
- Methyl Paraben : 0.15%
- Propyl Paraben: 0.03%


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- Sodium Alginate (Protanal LFR 5/60):0.3%
- Glycerine (Vegetable grade) :5%
- Microcrystalline Cellulose and Carboxymethyl cellulose Sodium (Avicel RC 591) :1.4%
- Sodium Hydroxide: q.s

Chemicals where a trade secret is claimed:

Information not Available

4 FIRST AID MEASURES

This section describes the initial care that should be given to an individual who has been exposed to the Chemical.

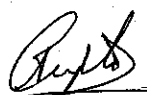
Symptoms Observed:

General advice Keep out of reach of children

- Inhalation** : If breathing is difficult, move to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
- Skin Contact** : Product does not irritate the skin.
- Eye Contact** : If irritation comes flush eyes with running water for a minimum of 15 minutes. Hold eyelids open during flushing. If Burning or stinging does not pass or feel continued discomfort, then Obtain medical attention.
- Ingestion** : Visit to physician if symptoms develop or persist

NOTES TO HEALTH PROFESSIONALS

- Medical Treatment** : Treat symptomatically
- Medical conditions caused or Aggravated by exposure** : Information not available
- Antidote** : Information not available


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5 FIRE FIGHTING MEASURES


This section provides recommendations for fighting a fire caused by the chemical.

- Fire and Explosion hazard** : Product is not Flammable
- Extinguishing media / equipment** : Dry Chemical Powder, Carbon Dioxide or AR Foam as appropriate for surrounding fire and materials
- Special firefighting procedure and Protective Measures** : Wear suitable Personal Protective Equipment
- Hazardous Combustion Products** : Under fire conditions – May emit toxic fumes, carbon monoxide. Toxic, corrosive or flammable thermal decomposition products may expect under fire condition

6 ACCIDENTAL RELEASE MEASURES

This section provides recommendations on the appropriate response to spills, leaks, or releases, including containment and clean up practices to prevent or minimize exposure to people, properties, or the environment. It may also include recommendations distinguishing between responses for large and small spills where the spill volume has a significant impact on the hazard.

- Personal Precautions** : Avoid excessive heat
- Environmental Precaution** : Dispose of waste material at an approved waste treatment facility in accordance with applicable local and federal regulation
- Clean - up Procedure** : Wash with plenty of water
- Decontamination Procedure** : No specific decontamination procedure has been identified
- Methods and materials used for Containment:** Information not Available
- Emergency Procedures** : Use PPE while handling the emergency


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7 HANDLING AND STORAGE

This section provides guidance on the safe handling practices and conditions for safe storage of chemicals.

Precautions for Safe Handling: Handle material with care. Avoid exposure to moisture, humid conditions and direct sunlight. This material should be handled as per instructions to ensure product integrity

Safe Storage : Keep container tightly closed. Keep container in a cool, well-ventilated area. Store at 20°C to 30°C. Keep away from all heat sources

Any Specific Storage Requirements: Information not available

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

This section indicates the exposure limits, engineering controls, and personal protective measures that can be used to minimize worker exposure.

Hazard category and Exposure Limits:

Appropriate Engineering Controls: - Refer section 9, 10, 11 and 12

Personal protective equipment Not Applicable

Ensure before use - Wash hands after handling and before eating

Respiratory protection : Not Applicable

Hand protection : Not Applicable

Eye protection : Not Applicable

Skin protection : Not Applicable


Exposure control : Not Applicable

Ventilation

Hygiene Measure : Wash hands and contaminated parts after handling. Promptly remove contaminated clothing. Wash contaminated clothing before reuse. Handle material in accordance with applicable good industrial hygiene and safety procedures.

9 PHYSICAL AND CHEMICAL PROPERTIES

This section identifies physical and chemical properties associated with the substance or mixture.


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Appearance and odour : Pink to Orange Coloured
Uniform Suspension

Vapour pressure : Information not available

Flash point : Product is not flammable

Melting range : Information not available

Specific gravity : Information not available

Relative density : Information not available

Solubility : Information not available

Odour threshold : Information not available

Freezing Point : Information not available

Partition Coefficient : Information not available

Vapour density : Information not available

Viscosity : Information not available

Boiling point : Information not available

Auto-ignition : Information not available

Flammability : Information not available

Explosive : Product is not flammable

Limits

pH : Information not available


Evaporation : Information not available

Rate

Decomposition Temperature : Information not available

Note: The Safety Data Sheet may not contain every item on the above list because information may not be relevant or is not available. Manufacturers may also add other relevant properties such as the dust deflagration index for combustible dust, used to evaluate a dust's explosive potential.

- 10 **STABILITY AND REACTIVITY**
This section describes the reactivity hazards of the chemical and the chemical stability information. This section is broken into three parts: Reactivity, Chemical Stability and Other.


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- Chemical Stability** : This product is expected to be stable till expiry period under prescribed conditions
- Reactivity** : Information is not available
- Conditions to avoid** :
- Incompatibility Material if any** : Avoid direct sun light
- Hazardous decomposition products** : Information not available
- Hazardous reactions** : Will not occur
- Hazardous polymerization** : Will not occur


11 TOXICOLOGICAL INFORMATION

This section identifies toxicological and health effects information or indicates that such data are not available.

Symptoms on Exposure:

Route of Exposure:

- Oral Toxicity** : Information not available **Sensitization** : Information not available
- Inhalation Toxicity** : Information not available **Genetic Toxicity** : Information not available
- Skin Effects** : Information not available **Carcinogenicity** : Information not available
- Eye Effects** : Information not available **Reproductive Effects** : Information not available
- Target Organ Effects** : Information not available
- Toxicity data** : Information not available
- ORL - RAT LD 50** : >10000 mg/kg (of API) **SCU - RAT LD 50** : Information not available
- ORL -MICE LD 50** : Information not available **SCU - MUS LD 50** : Information not available


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12 ECOLOGICAL INFORMATION (NON-MANDATORY)

This section provides information to evaluate the environmental impact of the chemical(s) if it were released to the environment.

Summary: Information not available

Ecotoxicity: No impact on environment.

Degradability: Information not available

13 DISPOSAL CONSIDERATIONS (NON-MANDATORY)

This section provides guidance on proper disposal practices, recycling or reclamation of the chemical(s) or its container and safe handling practices.

Description of appropriate disposal container to Use : Disposal of waste in accordance to all applicable local laws


Disposal Method Recommendations :

Physical and Chemical properties that can affect :

Disposal

Any special Precautions to be taken : Follow local and federal regulation

Regulatory Requirements :


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14 TRANSPORT INFORMATION (NON-MANDATORY)

This section provides guidance on classification information for shipping and transporting of hazardous chemical(s) by Road, Air, rail or sea.

This material is NOT a dangerous goods for the purpose of transportation

UN No: Information not available **UN Proper** Information not available
Shipping Name:

ADR Packing Group – Information not available **ADR Class** – Information not available

Additional Pictogram - Information not available

ADR **IATA** **GHS**

Environmental Hazards : Information not available

Any Special Precaution (if any) : Not Classified. Transportation of this product is not particularly restricted. It has no known significant hazards required special packaging, labelling or transportation of product / consignment for air, maritime or ground transport

15 REGULATORY INFORMATION (NON-MANDATORY)

This section identifies the safety, health and environmental regulations specific for the product that is not indicated anywhere else on the SDS.

Labelling according to EEC directives : As mentioned in Section 14 of this document

National legislation / regulations:

Any other regulatory information : Information not available


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16 OTHER INFORMATION

SDS Prepared on: 16.03.2017

Last Revision done date: NA

Changes done to previous version: NA

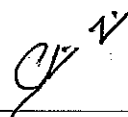
Therapeutic category of Material : Antifungal

Reference : MSDS of API

The information contained herein is based on the present state of our knowledge and does not therefore guarantee certain properties. The information given was obtained from sources which we believe are reliable. The information and recommendations given are to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. Recipients of material must take responsibility for observing existing laws, regulations and suitability of material for handling, transport and any particular purpose. We do not assume responsibility and expressly disclaim liability for loss, damage and expenses arising out of or in any way connected with the handling, storage, use and disposal of the product. Information mentioned in this document relates only to the specific material designated and may not be valid for such material used in combination with other material or in any process.



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Safety
Date: 18.03.2017



Approved By
Head Unit Quality
Date: 18.03.2017



Noted By
Unit Head
Date: 18.03.2017