

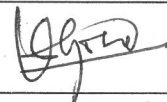

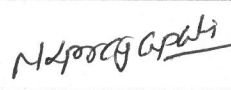
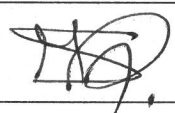
SAFETY DATA SHEETS

This SDS packet was issued with item:

078947791

N/A

| SAFETY DATA SHEET OF | | | | | |
|---|--------------|---|-----|----------------|------------|
| ✓ DRUG PRODUCT & INTERMEDIATE (NOT LIMITED TO) DRUG SUBSTANCE OF INHOUSE API / INTERMEDIATE OF INHOUSE API / IMPURITIES OF INHOUSE API / KEY STARTING MATERIAL (KSM) OF IN-HOUSE API/RAW MATERIAL (DEVELOPMENT) DRUG SUBSTANCE /NEW CHEMICAL ENTITY/ INTERMEDIATE/ IMPURITIES/ KSMS/ RAW MATERIAL (DISCOVERY) | | | | | |
| ✓ Drug Product & Intermediate Drug Substance of In-house API / Intermediate of In-house API / Impurities of In-house API / Key Starting Material (KSM) of In-House API /Raw material (Development) Drug Substance /New Chemical Entity/ Intermediate/ Impurities/ KSMS/Raw material(Discovery) | | Nystatin Cream USP (100,000 Units Per Gram) | | | |
| SDS No. | S1/000058/01 | Supersedes | Nil | Effective date | 01/04/2022 |

| ACTIVITIES | Department | Name | Signature | Date |
|-------------|--------------------------------------|----------------------|---|------------|
| Prepared by | Formulation Development Department | Nitin Somnathe | Nitin Somnathe <small>Digitally signed by Nitin Somnathe Date: 2022.02.19 14:04:14 +05'30'</small> | |
| Reviewed by | Formulation Development Department | Chandrakant Lokhande | Chandrakant Lokhande <small>Digitally signed by Chandrakant Lokhande Date: 2022.02.21 10:19:51 +05'30'</small> | |
| | Medicinal Chemistry Department | Prinivraj Goud |  | 28/02/2022 |
| | Clinical Research Department | SACHIN LATAD |  | 05/03/2022 |
| | Health Safety Environment Department | Mehul Prajapati |  | 16/03/2022 |
| Approved by | Quality | Hiren Shah |  | 01/04/2022 |

| | | | | | |
|--|----|-------------------|--------|-----------------|----|
| TITLE: FORMAT FOR SAFETY DATA SHEET | | | | | |
| Form No. : | -- | Reference SOP No. | QA-147 | SOP Version No. | 03 |

Torrent Pharmaceuticals Limited.

SAFETY DATA SHEET.

| | | |
|--|---------------------|-------------------------------|
| Name: Nystatin Cream USP (100,000 Units Per Gram) | | |
| SDS : S1/000058 | Version : 01 | Issue Date: 01/04/2022 |

Section-1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY.

| | | |
|-----|---|---|
| 1.1 | Product/Material identifier. | |
| | Product/Material Name. | Nystatin Cream USP (100,000 Units Per Gram) |
| 1.2 | Relevant identified use/s of the material and restrictions on use. | |
| | Recommended use: Nystatin cream is indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by Candida albicans and other susceptible Candida species. | |
| | Recommended restrictions: Use only as directed | |
| 1.3 | Manufacturer/Importer/Supplier/ Distributor identification. | |
| | Manufacturer: Torrent Pharmaceuticals Limited. Corporate office: Torrent House, Off. Ashram Road, Ahmedabad - 380009. Gujarat, India. | Telephone Number. : +91- (0)2764 -233671 |
| | | Fax Number.: + 91- (0)2764 - 233676 |
| | | Website.: www.torrentpharma.com |

Section-2: HAZARDS IDENTIFICATION.

| | | |
|-----|--|----------------|
| 2.1 | Classification of the substance. | |
| | Classification according to EC Regulation/ Directives/ Workplace Hazardous Materials Information System) WHMIS- Hazardous Materials Information System (HMIS)/ (Globally Harmonized System of classification & Labeling of Chemicals)GHS or National Fire Protection Association (NFPA) rating. | |
| | Physical : Not hazardous Health : Not hazardous | |
| 2.2 | Label elements. : Not hazardous in accordance with the GHS and OSHA Hazcom 2012. | |
| | Pictogram. | Not Applicable |
| | Signal word. | Not Applicable |
| | Precautionary statements. | Not Applicable |
| | Hazard statements. | Not Applicable |
| | Safety phrases. | Not Applicable |
| | Risk phrases. | Not Applicable |
| 2.3 | Emergency overview. | |
| | Not available | |

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2.4 Potential Health Effects.

Inhalation. No data available
Eye. No data available
Skin. No data available
Ingestion. No data available
Chronic. No data available

Section-3: COMPOSITION/INFORMATION ON INGREDIENTS.

| <i>Material Name</i> | <i>Chemical Abstract Service Registry Number (CAS)</i> | <i>European Inventory of Existing Chemical Substances (EINECS)/ European List of New Chemical Substances (ELINCS) No.</i> | <i>Concentration %</i> |
|----------------------|--|---|------------------------|
| Nystatin | 1400-61-9 | - | 100000 Units/g |
| Excipients | - | - | Proprietary |

Chemical name/Synonyms: Nystatin is a polyene antifungal antibiotic obtained from *Streptomyces noursei*
Therapeutic Category: antifungal antibiotic
Chemical Family: *Streptomyces noursei*

Section-4: FIRST AID MEASURES.
4.1 Description of First aid measures.

Inhalation. Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention
Eye. : Immediately flush eyes with water while lifting the upper and lower lids for several minutes. Get medical attention if irritation persists.
Skin.: This product is intended for use on the skin. For unintended contact, wash skin with soap and water. If irritation develops and persists, get medical attention. Remove contaminated clothing and wash it
Ingestion.: Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

4.2 Symptoms and effects of exposure.: May cause mild eye and skin irritation. Ingestion may cause gastrointestinal effects such as nausea or diarrhea.

4.3 General First aid procedures. : Not Applicable

4.4 Indications of immediate medical attention and overdose treatment. : if necessary:
 Immediate medical attention is generally not required

Section-5: FIRE FIGHTING MEASURES.

5.1 Extinguishing Media.: Use any media that is suitable for the surrounding fire.

5.2 Fire and explosion hazard. : Product is not flammable or combustible but may burn in a fire after the water has evaporated

5.3 Protective equipment and precautions for fire fighters.: Firefighters should wear positive

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pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

Section-6: ACCIDENTAL RELEASE MEASURES.

- 6.1 **Personal precautions, protective equipment and emergency procedures.:** Wear appropriate protective clothing and equipment as described in Section 8.
- 6.2 **Spills/Leaks response measures.:** Not available
- 6.3 **Environmental precautions.** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.
- 6.4 **Methods and materials for containment and cleaning up.:** Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

Section-7: HANDLING AND STORAGE.

- 7.1 **Precautions for safe handling.:** Avoid the generation of mists. Avoid eye contact. Avoid unintended contact with skin. Wash thoroughly with soap and water after handling.
- 7.2 **Conditions for safe storage.:** Store as indicated on product packaging

Section-8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

- 8.1 **Exposure limits & Engineering controls. :**
Nystatin : 100 ug/m3

- 8.2 **Individual protection measures.
Personal protective equipments.**

Respiratory protection.: None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved organic vapor/particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection & Protective clothing.: None required for normal use. Impervious gloves recommended for manufacturing operations.

Eye protection.: None required for normal use. Chemical safety goggles recommended for manufacturing operations

Hygiene measures. : No known

Section-9: PHYSICAL AND CHEMICAL PROPERTIES.

| | |
|------------------------|--|
| Physical state | |
| Color | Yellow to light tan powder |
| Odor | No data available |
| Molecular Formula | C ₄₇ H ₇₅ NO ₁₇ |
| Molecular Weight | 926.1 g/mol |
| pH | 6.00 – 8.00 |
| Freezing/Melting Point | No data available |
| Boiling Point | No data available |

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| | |
|--|---|
| <i>Flash Point</i> | No data available |
| <i>Density/Relative Density</i> | No data available |
| <i>Decomposition Temperature</i> | No data available |
| <i>Molar Refractivity</i> | No data available |
| <i>Vapour Pressure</i> | No data available |
| <i>Surface Tension</i> | No data available |
| <i>Auto-ignition Temperature</i> | No data available |
| <i>Flammability Limit</i> | No data available |
| <i>Explosive Properties</i> | No data available |
| <i>Evaporation rate</i> | No data available |
| <i>Index of Refraction</i> | No data available |
| <i>Solubility in water</i> | Practically insoluble |
| <i>Other solubility</i> | Freely soluble in dimethylformamide and in dimethyl sulfoxide; very slightly soluble in methanol; practically insoluble or insoluble in alcohol, in n-propyl alcohol, in n-butyl alcohol, in chloroform and in ether. |
| <i>International Chemical Identifier (InChI)</i> | No data available |

Section-10: STABILITY AND REACTIVITY.

- 10.1 **Stability:** Stable
- 10.2 **Incompatibility materials.:** Avoid oxidizing agents.
- 10.3 **Conditions to avoid. :** None known
- 10.4 **Hazardous decomposition products.:** Thermal decomposition may yield carbon oxides
- 10.5 **Hazard product polymerisation. :** Not available
- 10.6 **Possibility of Hazardous reactions. :** None known
- 10.7 **Reactivity:** Not reactive under normal conditions of use.

Section-11: TOXICOLOGICAL INFORMATION.

- 11.1 **Potential health effects through likely routes of exposure.**

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Respiratory or skin sensitization. :

Inhalation: Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract.

Eyes.

Contact may cause mild irritation with redness and tearing.

Skin.

No adverse effects are expected. Some users have reported skin irritation with burning, stinging or pain.

Ingestion.

Swallowing may cause gastrointestinal distress with nausea and diarrhea.

11.2 Information on Toxicological effects.

Acute toxicity. : Components are not actively toxic

Oral Rat: Median lethal dose (LD50) 10g/kg

Oral Mouse: LD50 Not available

Oral Rabbit: LD50 Not available

Oral Dog: LD50 Not available

Other toxicity data Not available

Skin corrosion/irritation. : Not available

Serious eye damage/eye irritation. : Not available

Chronic toxicology

Target Organ Effects Not known

Reproductive & developmental effects. Not known

Carcinogenicity. Not known

Mutagenicity Not known

Additional information.

Sensitization: Components are not known to be sensitizers.

Germ Cell Mutagenicity: No adverse effects are expected. Components are not germ cell mutagens.

Reproductive Toxicity: No adverse effects are expected. Components are not reproductive toxins.

Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP or OSHA

Section-12: ECOLOGICAL INFORMATION.

12.1 **Ecotoxicity Data. :** No data is available

12.2 **Persistence and Degradability.:** No data is available

12.3 **Bioaccumulative potential. :** No data is available

12.4 **Mobility in soil. :** No data is available

12.5 **Persistent Bio-accumulative and Toxic Chemical (PBT) and very Persistent and very Bio-accumulative (vPvB) assessment.**

12.6 **Other adverse effects :** Not known

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Section-13: DISPOSAL CONSIDERATIONS.

- 13.1 **Contaminated packaging disposal.:** No data is available
- 13.2 **Waste from residue/unused products.:** No data is available
- 13.3 **Disposal instructions.:**
 Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

Section-14: TRANSPORT INFORMATION.
14.1 Requisite transport info.

| | European agreement about international transport of hazardous goods by road (ADR)/ Rules about international railway transport of hazardous goods (RID) | International Maritime Dangerous Goods (IMDG) | International Air Transport Association (IATA) | United States Department of Transportation (US DOT) | Canada Transportation of Dangerous Goods (TDG) |
|-----------------------------------|--|--|---|--|---|
| UN-Number | | | | | |
| UN proper shipping name | | Not Regulated | Not Regulated | Not Regulated | Not Regulated |
| Transport hazard class(es) | Not Applicable | | | | |
| Packaging group | | | | | |
| Environmental hazards | | | | | |

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC code): Not applicable –product is transported only in packaged form

Special precautions: None known

14.2 Other compliance info for transport.
DOT

| | |
|--|---|
| Symbols: Not applicable | Hazard class: Not applicable |
| Label codes: Not applicable | Special provisions: Not applicable |
| Packaging: exceptions: Not applicable | Quantity limitations: Passenger aircraft/rail: No limit |
| Quantity limitations: Cargo aircraft only: Not applicable | Vessel storage: Not applicable |
| Hazardous material descriptions and shipping names: Not applicable | |

Air Transport IATA

International Civil Aviation Organization

ICAO/IATA subrisk: Not applicable

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(ICAO)/IATA Class: Not applicable
 UN ID Number: Not applicable
 Cargo only: Not applicable
 Packing instructions: Not applicable
 Passenger & Cargo: Not applicable
 Shipping name: Not applicable

Packing group: Not applicable
 Maximum Qty/Pack: Not applicable

Maritime transport

IMDG Class: Not applicable
 UN Number: Not applicable
 EMS Number: Not applicable
 Limited Quantities: Not applicable
 Shipping name: Not applicable

IMDG subrisk: Not applicable
 Packing group: Not applicable
 Special provisions: Not applicable
 Marine pollutant: Not applicable

Section-15: REGULATORY INFORMATION.

15.1 Safety, health and environmental regulations/legislation specific for the substance. U.S./European/GHS/International Regulatory Information.

Labeling in accordance with U.S./European/International Regulations

Hazard symbol. Not applicable
Risk phrases Not applicable
Safety phrases Not applicable
WGK (Water Danger/Protection) Not applicable

Canada

Canadian CEPA This product is a drug and not subject to CEPA regulations
Canadian WHMIS Drugs are exempt from WHMIS

Classification:

US Federal Toxic Substances Control Act (TSCA) Not applicable
 This product is a drug and not subject to TSCA
Superfund Not applicable
Amendments and Reauthorization Act (SARA) Components. Not applicable

SARA Hazard Category (311/312):
 EPA SARA 313:

Not Hazardous
 This Product contains the following chemicals regulated under SARA Title III, section 313: None
 This product contains the following chemicals regulated under SARA Title III section 313: None

This Product has been classified under the CPR and this SDS discloses information elements required by the CPR

Inventory status.

| Country(s) or | Inventory name | On inventory |
|---------------|----------------|--------------|
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| | | |
|----------------|----------------|-----------------|
| region | | (yes/no) |
| Not applicable | Not applicable | No |
| | | |

Section-16: OTHER INFORMATION.

Attention: No data is available
Disclaimer: No data is available
Data Sources: No data is available

NFPA Rating: Health = 1 Flammability = 1 Instability = 0
HMIS Rating: Health = 1 Flammability = 1 Physical Hazard = 0

Prepared by:

Revision summary:

| Version | Section | Reason for revision |
|---------|--------------|---------------------|
| 01 | All sections | New MSDS |

| | | | |
|-----------------------------------|--------|-----------------|----|
| TITLE: CHANGE HISTORY CARD | | | |
| Reference SOP No. | QA-022 | SOP Version No. | 06 |

Name of Product: Nystatin Cream, USP 100,000 units per gram

| SR. NO. | DOCUMENT NO. | VERSION NO. | CHANGES MADE | REASON FOR CHANGE | CCF NO. | EFFECTIVE DATE |
|---------|--------------|-------------|--------------|-------------------|---------|----------------|
| 1. | S1/000058 | 01 | NA | New Document | NA | 01/04/2022 |

| | |
|---------------------------------|-------------------------------|
| Prepared By (Initiator): | Approved By (Quality): |
| Sign: <i>BS</i> | Sign: <i>Mrudyul Bumbatia</i> |
| Name: <i>Bhanini</i> | Name: <i>Mrudyul Bumbatia</i> |
| Date: <i>19/02/2022</i> | Date: <i>01/04/2022</i> |