SAFETY DATA SHEET

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

Product Identifier

Material Name: Rifabutin Capsules

Trade Name: MYCOBUTIN; ANSATIPIN; ATIPICIN

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antibiotic agent.

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
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Emergency telephone number: International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not required
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIFABUTIN CAPSULES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Revision date: 02-May-2018
Version: 3.1
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS</th>
<th>GHS Classification %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Red iron oxide</td>
<td>Not assigned</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Rifabutin</td>
<td>72559-06-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Sodium Lauryl Sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Silica gel, amorphous</td>
<td>112926-00-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known

Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment and Emergency Procedures**
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Environmental Precautions**
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Methods and Material for Containment and Cleaning Up**
- **Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
- **Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

**Precautions for Safe Handling**
Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**Conditions for Safe Storage, Including any Incompatibilities**
- **Storage Conditions:** Store as directed by product packaging.
- **Specific end use(s):** Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**
Refer to available public information for specific member state Occupational Exposure Limits.

**Microcrystalline cellulose**
- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- Australia TWA 10 mg/m³
- Belgium OEL - TWA 10 mg/m³
- Estonia OEL - TWA 10 mg/m³
- France OEL - TWA 10 mg/m³
- Ireland OEL - TWAs 10 mg/m³
- Latvia OEL - TWA 2 mg/m³
- OSHA - Final PELS - TWAs: 15 mg/m³
- Portugal OEL - TWA 10 mg/m³
- Romania OEL - TWA 10 mg/m³
- Russia OEL - TWA 6 mg/m³
- Spain OEL - TWA 10 mg/m³
- Switzerland OEL -TWAs 3 mg/m³
- Vietnam OEL - TWAs 10 mg/m³
- 5 mg/m³

**Titanium dioxide**
The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

**Rifabutin**

**Pfizer Occupational Exposure Band (OEB):** OEB 2 (control exposure to the range of 100μg/m³ to < 1000μg/m³)

**Exposure Controls**

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
**SAFETY DATA SHEET**

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**Revision date:** 02-May-2018

**Version:** 3.1

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**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Hands:** Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Capsule</th>
<th>Color:</th>
<th>Reddish brown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available</td>
<td>Odor Threshold:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

| Solvent Solubility: | No data available |
| Water Solubility: | No data available |
| pH: | No data available |
| Melting/Freezing Point (°C): | No data available |
| Boiling Point (°C): | No data available |
| Partition Coefficient: (Method, pH, Endpoint, Value) | | |
| Gelatin | No data available |
| Microcrystalline cellulose | No data available |
| Sodium Lauryl Sulfate | No data available |
| Magnesium Stearate | No data available |
| Silica gel, amorphous | No data available |
| Titanium dioxide | No data available |
| Red iron oxide | No data available |
| Rifabutin | Measured 6-8 Log D 3.2 |
| Decomposition Temperature (°C): | No data available |
| Evaporation Rate (Gram/s): | No data available |
| Vapor Pressure (kPa): | No data available |
| Vapor Density (g/ml): | No data available |
| Relative Density: | No data available |

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SAFETY DATA SHEET

Material Name: Rifabutin Capsules
Revision date: 02-May-2018

Viscosity: No data available

Flammability:
- Autoignition Temperature (Solid) (°C): No data available
- Flammability (Solids): No data available
- Flash Point (Liquid) (°C): No data available
- Upper Explosive Limits (Liquid) (% by Vol.): No data available
- Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions
- Oxidizing Properties: No data available
- Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
- Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
- Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on blood, kidneys, liver, male reproductive system, the developing fetus. Prolonged or repeated inhalation may cause nose, throat and lung irritation. (based on components).

Known Clinical Effects: Clinical use of this drug has caused skin rash fever, nausea, vomiting, red discoloration of urine, eye abnormalities, neutropenia, joint pain, abdominal pain, muscle pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Acute Toxicity: (Species, Route, End Point, Dose)

Microcrystalline cellulose
- Rat Oral LD50 > 5000 mg/kg
- Rabbit Dermal LD50 > 2000 mg/kg

Sodium Lauryl Sulfate
- Rat Oral LD 50 1288 mg/kg
- Rat Sub-tenon injection (eye) LD 50 210mg/kg

Titanium dioxide
- Rat Oral LD50 > 7500 mg/kg
- Rat Subcutaneous LD50 50 mg/kg

Rifabutin
- Mouse Oral LD 50 3322 mg/kg
- Rat Para-periosteal LD 50 51mg/kg
- Dog Oral LD 50 >2000mg/kg
- Rat Oral LD 50 >5000mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.
11. TOXICOLOGICAL INFORMATION

Irritation / Sensitization: (Study Type, Species, Severity)

Microcrystalline cellulose
Skin Irritation  Rabbit  Non-irritating
Eye Irritation  Rabbit  Non-irritating

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Sodium Lauryl Sulfate
3 Day(s)  Rat  Oral  75 mg/kg  LOAEL  Liver, Blood

Magnesium Stearate
13 Week(s)  Rat  Oral  1092 g/kg  LOAEL  Liver

Rifabutin
13 Week(s)  Rat  Oral  9100 mg/kg  LOAEL  Blood, Kidney, Liver
13 Week(s)  Mouse  Oral  100 mg/kg/day  LOAEL  Liver
1 Year(s)  Rat  Oral  29,120 mg/kg  LOAEL  Blood, Endocrine system
1 Year(s)  Mouse  Oral  32 mg/kg/day  LOAEL  Blood

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Rifabutin
Embryo / Fetal Development  Rat  Oral  200 mg/kg/day  NOEL  Fetotoxicity
Embryo / Fetal Development  Rat  Oral  40 mg/kg/day  LOAEL  Fetotoxicity, Maternal Toxicity, Not Teratogenic
Embryo / Fetal Development  Rabbit  Oral  80 mg/kg/day  LOAEL  Fetotoxicity, Maternal Toxicity, Not Teratogenic
Reproductive & Fertility-Males  Rat  Oral  160 mg/kg/day  LOAEL  Fertility

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Rifabutin
In Vitro Bacterial Mutagenicity (Ames)  Salmonella, E. coli  Negative
In Vitro Chromosome Aberration  Human Lymphocytes  Negative
In Vitro Micronucleus  Chinese Hamster Ovary (CHO) cells  Negative
In Vivo Micronucleus  Mouse Bone Marrow  Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Rifabutin
2 Year(s)  Mouse  Oral, in feed  180 mg/kg/day  NOAEL  Not carcinogenic
2 Year(s)  Rat  Oral, in feed  60 mg/kg/day  NOAEL  Not carcinogenic

Carcinogen Status:
See below

Silica gel, amorphous
IARC:  Group 3 (Not Classifiable)

Titanium dioxide
IARC:  Group 2B (Possibly Carcinogenic to Humans)
12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: Partition Coefficient: (Method, pH, Endpoint, Value)
Rifabutin
Measured 6-8 Log D 3.2

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Gelatin
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
15. REGULATORY INFORMATION

Microcrystalline cellulose
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 232-674-9

Red iron oxide
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Rifabutin
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 6
- EU EINECS/ELINCS List: Not Listed

Sodium Lauryl Sulfate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: 205-788-1

Titanium dioxide
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: carcinogen 9/2/2011 airborne, unbound particles of respirable size
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 236-675-5

Magnesium Stearate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 209-150-3

Silica gel, amorphous
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed
16. OTHER INFORMATION

Data Sources:    Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision:    Updated Section 2 - Hazard Identification. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date:    02-May-2018


Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet