1. Product and Company Identification

PRODUCT NAME: PRIFTIN® (Rifapentine) Tablets
150 mg

Substance name: Rifapentine

Supplier:
Sanofi-aventis U.S. LLC
A SANOFI COMPANY
55 Corporate Drive
Bridgewater, NJ 08807

24-Hour Transport Emergency, US (Chemtrec):	**(800) 424-9300**
24-Hour Transport Emergency, outside US (Chemtrec):	**(703) 527-3887**
US Customer Service	**(800) 207-8049**
24-Hour Emergency, sanofi-aventis US:	**(908) 981-5550**

Product use: Pharmaceutical product.

2. Hazards Identification

2.1 Classification in accordance with 29 CFR 1910.1200

Classification of the finished drug product is not required according to OSHA 29 CFR 1910.1200. The following information is provided for the drug substance, rifapentine:

Classification: Acute toxicity, oral – Category 4

2.2 Label elements in accordance with 29 CFR 1910.1200

Labeling of the finished drug product is not required according to OSHA 29 CFR 1910.1200. The following information is provided for the drug substance, rifapentine:

Signal Word: Warning

Hazard Statement(s): Harmful if swallowed

Symbol(s): Exclamation mark

Precautionary Statement(s):

- Prevention: Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product.
- Response: If swallowed: Call a poison center if you feel unwell. Rinse mouth.
- Storage: Not required.
- Disposal: Dispose of contents in accordance with applicable regional, national and local laws and regulations.

2.3 Hazards Not Otherwise Classified (HNOC)

Not classified.

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3. Composition/Information on Ingredients

Chemical Name:	**Common Name:**	**CAS #:**	**Percentage or concentration range**
3-(((4-Cyclopentyl-1-piperazinyl)-imino)methyl)rifamycin	Rifapentine	61379-65-5	150 mg per tablet

Inactive Ingredients: Calcium stearate, disodium EDTA, FD&C Blue No. 2 aluminum lake, hydroxypropyl cellulose, hypromellose USP, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, propylene glycol, sodium ascorbate, sodium lauryl sulfate, sodium starch glycolate, synthetic red iron oxide, and titanium dioxide.

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4. First Aid Measures

4.1 First aid procedures

Eye contact: In case of contact with dust from broken tablets, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention.

Skin contact: In case of contact with broken tablets, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists.

Ingestion: If swallowed, call a poison center or physician if you feel unwell. Do NOT induce vomiting unless directed to do so by a physician. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water.

Inhalation: If dust from broken tablets is inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. Get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Hypersensitivity reactions, hepatotoxicity. Anemia, lymphopenia, neutropenia, increased ALT, arthralgia, conjunctivitis, headache, vomiting, nausea, diarrhea, rash, pruritus, anorexia and lymphadenopathy.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically and supportively.

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5. Fire Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media: All means: water, carbon dioxide, foam or dry chemical.

Unsuitable extinguishing media: Strong water jet.

5.2 Specific hazards arising from the chemical

Hazardous combustion products: Carbon monoxide, carbon dioxide, oxides of nitrogen.

5.3 Special Protective Equipment and Precautions for Fire-fighters

In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. Move container from fire area if you can do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal.

6. Accidental Release Measures

6.1 Personal precautions and Protective Equipment:

Eye protection, respiratory protective equipment, and suitable protective clothing should be worn if significant dust emissions are generated from broken or crushed tablets.

6.2 Emergency Procedures:

Follow local workplace procedures. Prevent the product from entering the environment. Avoid discharges to sewers, drains, waterways, or onto the ground.

6.3 Methods for containment:

Vacuum or scoop up, moisten any dust with water before collection with a shovel or broom.

6.4 Methods for clean-up:

Place material in suitable container for disposal. Wash the floor with plenty of water, absorb or retain the cleaning water for disposal.

7. Handling and Storage

7.1 Precautions for Safe Handling

Use with adequate ventilation. Avoid breathing dust if tablets are crushed or spilled. Do not get dust in eyes or on skin. Wash thoroughly after handling.

7.2 Conditions for Safe Storage

Store at 25°C (77°F). Protect from excessive heat and humidity. Keep container tightly closed. Avoid exposure to light.

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Sanofi-aventis occupational exposure limit, rifapentine: 0.5 mg/m^3, 8-hour TWA.

8.2 Appropriate Engineering Controls

Provide adequate ventilation. No other specific controls are needed under normal handling conditions.

8.3 Individual Protection Measures

Eye/face protection: Safety glasses or safety goggles should be worn if there is a potential for dust exposure from broken or crushed tablets.

Skin protection: Suitable protective gloves should be worn if handling the unfinished product or broken or crushed tablets.

Respiratory protection: None normally required. Approved respiratory protection should be worn if there is a potential for exposure to dust from handling operations or from broken or crushed tablets.

General hygiene considerations: Suitable work clothes. Wash hands before breaks and at the end of the work shift.

9. Physical and Chemical Properties

Appearance: Dark pink tablets.
Odor: No data available.
Odor threshold: No data available.
pH: No data available.
Melting point (rifapentine): 179 - 180 °C
Initial boiling point/boiling point range: Not applicable.
Flash point: Not applicable.
Evaporation rate: Not applicable.
Flammability: No data available.
Upper/lower flammability or explosive limits: No data available.
Vapor pressure: Not applicable.
Vapor density: Not applicable.
Relative density: No data available.
Solubility: No data available.

Partition coefficient: n-octanol/water: No data available.
Auto-ignition temperature: No data available.
Decomposition temperature (rifapentine): 153 °C
Viscosity: No data available.

10. Stability and Reactivity

10.1 Reactivity

Not a reactive material under normal handling conditions.

10.2 Chemical Stability

Stable under normal handling conditions.

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to Avoid

Keep away from heat, sparks and flames.

10.5 Incompatible materials

Strong oxidizing and reducing agents.

10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide, oxides of nitrogen.

11. Toxicological Information

The following information is for the active ingredient rifapentine unless otherwise noted:

Information on likely routes of exposure: Exposure not expected under normal use. Dust from broken or crushed tablets could result in exposure to eyes, skin and respiratory tract.

Symptoms related to the physical, chemical and toxicological characteristics: Anemia, lymphopenia, neutropenia, increased ALT, arthralgia, conjunctivitis, headache, vomiting, nausea, diarrhea, rash, pruritus, anorexia and lymphadenopathy.

Effects of short-term (acute) exposure: Hypersensitivity reactions.

Effects of long-term (chronic) exposure: Hepatotoxicity.

Acute toxicity (LD50):
Oral route, rat: 2,350 mg/kg
Oral route, mouse: 3,210 mg/kg
Intraperitoneal (IP) route, rat: 585 mg/kg
Intraperitoneal (IP) route, mouse: 710 mg/kg

Skin corrosion/irritation: No data available.

Serious eye damage/irritation: No data available.

Sensitization: No data available.

Specific target organ toxicity – single exposure (STOT-SE): No data available.

Specific target organ toxicity – repeated exposure (STOT-RE): No data available.

Carcinogenicity: Hepatocellular carcinomas were increased in male NMRI mice (Harlan Winklemann) which were treated orally with rifapentine for two years at or above doses of 5 mg/kg/day (0.04 times the recommended human dose based on body surface area conversions). In a two year rat study, there was an increase in nasal cavity adenomas in Wistar rats treated orally with rifapentine at 40 mg/kg/day (0.6 times human dose based on body surface area conversions).

Not listed by NTP, not found to be a potential carcinogen by IARC or OSHA.

Titanium dioxide has been classified by IARC as 2B: Possibly carcinogenic to humans. Tumors were observed at high dose in animal studies by inhalation and intratracheal administration. Tumors were not observed by other routes.

Reproductive toxicity and teratogenicity: There are no adequate and well controlled trials of PRIFTIN® in pregnant women; however, there are limited pregnancy outcome data reported from women enrolled in clinical trials of various PRIFTIN® treatment regimens for active tuberculosis and latent tuberculosis infection. The reported rate of spontaneous abortion following PRIFTIN exposure did not represent an increase over the background rate of spontaneous abortion reported in the general population. Further interpretation of these data is limited by the quality of clinical trial adverse event reporting. In animal reproduction and developmental toxicity studies, rifapentine produced fetal harm and was teratogenic at doses less than and similar to the recommended human dose.

Mutagenicity: Rifapentine was negative in the following genotoxicity tests: in vitro gene mutation assay in bacteria (Ames test); in vitro point mutation test in Aspergillus nidulans; in vitro gene conversion assay in Saccharomyces cerevisiae; host-mediated (mouse) gene conversion assay with Saccharomyces cerevisiae; in vitro Chinese hamster ovary cell/hypoxanthineguanine-phosphoribosyl transferase (CHO/HGPRT) forward mutation assay; in vitro chromosomal aberration assay; and in vivo mouse bone marrow micronucleus assay.

Aspiration hazard: Not applicable.

12. Ecological Information

The following information is for the active ingredient rifapentine unless otherwise noted:

12.1. Ecotoxicity

Fish toxicity (LC50): > 100 mg/l
Species: Danio rerio
Exposure duration: 96 h

Toxicity on invertebrates (EC50): 3,300 mg/l
Species: Daphnia magna
Exposure duration: 24 h

Toxicity on invertebrates (EC50): 3,300 mg/l
Species: Daphnia magna
Exposure duration: 48 h

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Other adverse effects

No data available.

13. Disposal Considerations

13.1 Disposal of product waste

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

13.2 Disposal of packaging waste

Dispose of in a safe manner in accordance with federal, state and local environmental regulations. Empty packages, containers or liners may contain product residue.

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14. Transport Information

14.1 Basic shipping information, finished product

U.S. DOT	Not a regulated material.
ICAO/IATA	Not a regulated material.
IMDG	Not a regulated material.

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15. Regulatory Information

US Regulations
CERCLA Hazardous Substance List (40 CFR 302.4): Not listed.
Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): Not listed.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): Not listed.
SARA Title III:
Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): Not listed.
Section 313 Toxic Release Inventory (40 CFR 372): Not listed.

State Regulations
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): Titanium dioxide (airborne, unbound particles of respirable size).
Massachusetts Right-To-Know List: Titanium dioxide.
New Jersey Right-To-Know List: Titanium dioxide.
Pennsylvania Right-To-Know List: Titanium dioxide.

16. Other Information

Other Information: The information contained herein is based upon data considered true and accurate. Sanofi-aventis U.S. LLC. makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Abbreviations and Acronyms
CAS: Chemical Abstracts Service
DOT: U.S. Department of Transportation
EST: Eastern standard time (U.S.)
IATA: International Air Transport Association
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
OEL: Occupational Exposure Limit
PPE: Personal Protection Equipment
SDS: Safety Data Sheet
STEL: Short-term exposure limit
TWA: Time-weighted average
U.S.: United States

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Second version.