

SAFETY DATA SHEET

Etravirine Tablets 100 mg and 200 mg

Version: 2

Issue Date: 06/29/2022

1. IDENTIFICATION:

Product Name: Etravirine Tablets 100 mg and 200 mg

Recommended Use: Rx Pharmaceutical for human use as anti-retroviral (To Treat HIV Infection).

Used Advised Against: Not Available

Distributor: Leading Pharma, LLC
3 Oak Rd
Fairfield NJ, 07004
Emergency: (973) 276-9600 or call 911
Information: (973) 276-9600

Manufacturer: Carnegie Pharmaceuticals, LLC
600 Delran pkwy
Delran, NJ 08075
Emergency: (732) 783-7011 or call 911
Information: (732) 783-7011

2. HAZARDS IDENTIFICATION:

Hazard Classification:

This product is a mixture that has not been fully tested as a whole. Not a hazardous substance.

Label Element

Signal Word(s): Not Applicable

Hazard Statements: Not Applicable

Precautionary Statements:

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

Use PPE as required. If exposed or concerned: Get medical attention.

Description of other hazards: Not Available

3. COMPOSITION / INFORMATION ON INGREDIENTS:

Contains:

| <u>Active Ingredient:</u> | <u>CAS Number:</u> | <u>Strength:</u> |
|---------------------------|--------------------|--------------------|
| Etravirine | 269055-15-4 | 100 mag and 200 mg |

In-active ingredients are no-hazardous.

4. FIRST AID MEASURES:

General: In case of accident involving illness, seek medical advice immediately.

Eye Contact: Remove contact lenses. Immediately flush eyes with plenty of water. Obtain medical attention.

Skin Contact: Remove contaminated clothing. Flush skin with plenty of water. Obtain medical attention.

Inhalation: Remove to fresh air. Seek medical advice immediately. If not breathing, trained personnel

SAFETY DATA SHEET

Etravirine Tablets 100 mg and 200 mg

Version: 2

Issue Date: 06/29/2022

should give artificial respiration. If difficulty in breathing, trained personnel should give oxygen.

Ingestion: Seek medical advice immediately. Provide container labeling or SDS if possible.

5. **FIRE FIGHTING MEASURES:**

Extinguishing media: Use extinguishing media appropriate to the surrounding fire.

Special considerations: Toxic gases and vapors may be released if involved in a fire.

6. **ACCIDENTAL RELEASE MEASURES:**

Small spill: Utilize appropriate personal protective equipment. Gather spilled material and place in a glass or plastic container. Assess and document the amount of material collected.

Large spill: Contain spill to the extent possible using available absorbents. Prevent entry into water systems, surface waters, or groundwater. Notify the appropriate emergency response personnel. Do not attempt clean-up without appropriate protective equipment.

7. **HANDLING AND STORAGE:**

Store in the original bottle and protect from moisture.

Packaging Material: HDPE Bottle with CRC cap.

8. **EXPOSURE CONTROLS / PERSONAL PROTECTION:**

Personal Protection Recommendations:

Ventilation: A local and/or general exhaust system is recommended to minimize airborne contaminants.

Respiratory Protection: Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.

Protection of Hand: Protective gloves should be worn when handling unpackaged product and raw materials in the manufacturing setting.

Body Protection: Wear clean, body-covering protective clothing that is suitable for the task being performed.

Eye Protection: Utilize safety eyewear that complies with an approved standard when protection from splash, mist or dust is required.

General hygienic measures: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment.

9. **PHYSICAL AND CHEMICAL PROPERTIES:**

Product Strength: Etravirine Tablets 100 mg and 200 mg

Physical State: Solid

Color: White to off-white Tablets

Shape: N/A

Deboss/Imprint: CP112 (100 mg) CP113 (200 mg)

Odor: NA

pH: NA

Boiling point: Not Available

Odor threshold: Not available

pH: Not available

Melting point/melting range: Not available

Boiling point/boiling range: Not available

Flash point: Not available

Evaporation rate: Not available

Flammability: Not available

SAFETY DATA SHEET

Etravirine Tablets 100 mg and 200 mg

Version: 2

Issue Date: 06/29/2022

Upper/lower flammability or explosive limits: Not available

Auto ignition temperature: Not available

Danger of explosion: Not available

Vapor pressure: Not available

Vapor density: Not available

Relative density: Not available

Solubility in/Miscibility with water: Not Soluble

10. **STABILITY AND REACTIVITY:**

Reactivity: Not Available

Chemical stability: Not Available

Conditions to avoid: Not Available

Incompatible materials: Strong Oxidizing agent

Hazardous decomposition products: Hazardous decompositions products formed under fire conditions. nitrogen oxide and carbon oxides

11. **TOXICOLOGICAL INFORMATION:**

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Acute toxicity: LD50 Oral – rat- 980 mg/kg for Etravirine

Potential routes of exposure/potential health effects

Skin: No data available

Eye: No data available

Carcinogenic effects: Etravirine is not carcinogenic to human

Mutagenic effects: Etravirine is non-mutagenic

Reproductive toxicity: Etravirine Not a teratogenic substance

Sensitization: No Data available

Target organs: Not Available

12. **ECOLOGICAL INFORMATION:**

Not established. This product is a mixture that has not been tested as a whole.

13. **DISPOSAL CONSIDERATIONS:**

Ensure compliance with local, state and federal regulations.

14. **TRANSPORT INFORMATION:**

Refer to the bill of lading for proper shipping information.

Special considerations: N/A

15. **REGULATORY INFORMATION:**

Individual containers are labeled in accordance with U.S. FDA regulations for finished pharmaceutical products.

Drug Status: Rx Only

Schedule: Non-controlled

16. **OTHER INFORMATION:**

Not applicable

SAFETY DATA SHEET

Etravirine Tablets 100 mg and 200 mg

Version: 2

Issue Date: 06/29/2022

The information herein is provided in good faith and is believed to be accurate as of the effective date shown. However, no warranty, express or implied is given. Carnegie Pharmaceutical, LLC makes no representation as to the comprehensiveness or accuracy of the information. Conditions of use are beyond Carnegie Pharmaceutical, LLC's control and therefore users are responsible to verify this data under their own operating conditions to determine whether the product is suitable for their particular purposes, and they assume all risks of their use, handling, and disposal of the product. Carnegie Pharmaceutical, LLC expressly disclaims any and all liability as to any results obtained, or arising from, any use of this publication or reliance upon information contained herein.
