

Safety Data Sheet

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

Product Identifier

Material Name: Erlotinib Tablets 25 mg, 100 mg & 150 mg

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use:

Pharmaceutical product used as Antineoplastic

Details of the Supplier of the Safety Data Sheet

Shilpa Medicare Limited,
S-20 to S-26, Pharmaceutical Formulations SEZ;
TSIIC, Green Industrial Park, Polepally,
Jadcherla, Mahabubnagar,
Telangana 509301, India (IND)

Emergency telephone number: +91 9652400511

Contact E-Mail: info@vbsilpa.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Health Hazards:

- 3.1 Acute toxicity (Category 4)
H302 Harmful if swallowed.

Label Elements

Signal Word: Warning

Precautionary Statements:

- P260 Do not breathe dust
- P309 + P311 IF exposed or you feel unwell: Call a POISON CENTER or doctor/physician.
- P273 Avoid release to the environment.



Other Hazards

Note - no information available

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	%
Erlotinib Hydrochloride	183319-69-9	34.58%
Microcrystalline Cellulose	9004-34-6	28.88%

Lactose Monohydrate	10039-26-6	22.17%
Sodium Starch glycolate	9063-38-1	7.60%
Sodium lauryl Sulfate	151-21-3	2.53%
Magnesium Stearate	557-04-0	1.33%

4. FIRST AID MEASURES

Description of First Aid Measures

First-aid Measures General:	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).
First-aid Measures After Inhalation:	Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.
First-aid Measures After Skin Contact:	Remove contaminated clothing. Gently wash with plenty of soap and water followed by rinsing with water for at least 15 minutes. Call a POISON CENTER or doctor/physician if you feel unwell. Wash contaminated clothing before reuse.
First-aid Measures After Eye Contact:	Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.
First-aid Measures After Ingestion:	Do not induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor/physician.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms/Injuries: Pharmaceutical.	When handling in workplace settings, in quantities that are most likely above the therapeutic dose, this product may be harmful if absorbed through the eyes, skin, or respiratory tract.
Symptoms/Injuries After Inhalation:	If tablet is crushed: May cause respiratory irritation.
Symptoms/Injuries After Skin Contact:	May cause an allergic skin reaction.
Symptoms/Injuries After Eye Contact:	If tablet is crushed: Causes eye irritation.
Symptoms/Injuries After Ingestion:	May be harmful if swallowed.
Chronic Symptoms:	Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.

Indication of the Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

5. FIRE FIGHTING MEASURES

Extinguishing Media:

Suitable Extinguishing Media:	Water spray, fog, alcohol-resistant foam, dry chemical, carbon dioxide.
Unsuitable Extinguishing Media:	Do not use a heavy water stream. Use of heavy stream of water may spread fire.

Special Hazards Arising from the Substance or Mixture

Fire Hazard:	Not considered flammable but may burn at high temperatures.
Explosion Hazard:	Product is not explosive.
Reactivity:	Hazardous reactions will not occur under normal conditions.

Advice for Fire-Fighters

Precautionary Measures Fire:	Exercise caution when fighting any chemical fire.
Firefighting Instructions:	Use water spray or fog for cooling exposed containers.
Protection During Firefighting:	Do not enter fire area without proper protective equipment, including respiratory protection.
Other Information:	Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

General Measures:	Use only as directed.
For Non-emergency Personnel	
Protective Equipment:	Use appropriate personal protection equipment (PPE).
Emergency Procedures:	Evacuate unnecessary personnel.
For Emergency Responders	
Protective Equipment:	Equip cleanup crew with proper protection.
Emergency Procedures:	Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

Environmental Precautions

For Containment:	Contain and collect as any solid.
Methods for Cleaning Up:	Clean up spills immediately and dispose of waste safely. Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Contact competent authorities after a spill.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Additional Hazards When Processed:	Avoid breaking or crushing tablets.
Hygiene Measures:	Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

Conditions for Safe Storage, Including any Incompatibilities

Technical Measures:	Comply with applicable regulations.
Storage Conditions:	Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.
Incompatible Products:	Strong acids, strong bases, strong oxidizers.
Storage Temperature:	25 °C (77 °F); excursions permitted to 15 °C - 30 °C (59 °F - 86 °F)

Specific End Use(s)

Non-small cell lung cancer. For professional use only.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the

manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

Exposure Controls

Appropriate Engineering Controls: Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.

Personal Protective Equipment : Gloves.



Materials for Protective Clothing	:	Chemically resistant materials and fabrics.
Hand Protection	:	Wear chemically resistant protective gloves.
Eye Protection	:	Chemical goggles or safety glasses.
Skin and Body Protection	:	Wear suitable protective clothing.
Respiratory Protection	:	None required under normal product handling conditions. Use NIOSH-approved dust mask if dust has the potential to become airborne.
Environmental Exposure Controls	:	Do not allow the product to be released into the environment.
Consumer Exposure Controls	:	Do not eat, drink or smoke during use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties Physical State	:	Solid
Appearance	:	25 mg tablets: White to off white round, biconvex, film-coated tablets, debossed with "S13" on one side and plain on other side. 100 mg tablets: White to off white round, biconvex, film-coated tablets, debossed with "S12" on one side and plain on other side. 150 mg tablets: White to off white round, biconvex, film-coated tablets, debossed with "S11" on one side and plain on other side.
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	Aqueous solubility of erlotinib hydrochloride is dependent on pH with increased solubility at a pH of less than 5 due to protonation of the secondary amine. Over the pH range of 1.4 to 9.6, maximal solubility of approximately 0.4 mg/mL occurs at a pH of approximately 2.
Evaporation Rate	:	No data available

Melting Point	:	No data available
Freezing Point	:	No data available
Boiling Point	:	No data available
Flash Point	:	No data available
Auto-ignition Temperature	:	No data available
Decomposition Temperature	:	No data available
Flammability (solid, gas)	:	No data available
Vapor Pressure	:	No data available
Relative Vapor Density at 20 °C	:	No data available
Relative Density	:	No data available
Solubility	:	Very slightly soluble in water, slightly soluble in methanol and practically insoluble in acetonitrile, acetone, ethyl acetate and hexane.
Partition Coefficient: N-Octanol/Water	:	No data available
Viscosity	:	No data available
Molecular Weight Of Active Ingredient	:	429.90 g/mol

Other Information: No additional information available.

10. STABILITY AND REACTIVITY

Reactivity:	Hazardous reactions will not occur under normal conditions.
Chemical Stability:	Stable under recommended handling and storage conditions (see section 7).
Possibility of Hazardous Reactions:	Hazardous polymerization will not occur.
Conditions to Avoid:	Direct sunlight. Extremely high or low temperatures. Ignition sources. Incompatible materials.
Incompatible Materials:	Strong acids, strong bases, strong oxidizers.
Hazardous Decomposition Products:	Carbon oxides (CO, CO ₂). Nitrogen oxides. Hydrogen chloride gas.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Acute Toxicity: Not classified

Erlotinib (183321-74-6)

Minimum Lethal Dose Oral Rat	1000 mg/kg
Minimum Lethal Dose Oral Mouse	2000 mg/kg
Minimum Lethal Dose Oral Dog	> 200 mg/kg

Minimum Lethal Dose Intravenous Rat
Minimum Lethal Dose Intravenous Mouse
Minimum Lethal Dose Intravenous Dog
Additional information

50 mg/kg
 75 mg/kg
 > 15 mg/kg
 Acute effects included a transient decrease in activity and irregular respiration (2000 mg/kg, oral) and a decrease in body weight gain (500, 1000, 2000 mg/kg, oral) in mice and rats. Acute effects in dogs included emesis, decreased activity, pale gums, cold skin, tremors, salivation, and/or ataxia (200 mg/kg, oral). Intravenous administration produced convulsions at 25 mg/kg or greater in mice, or 35 mg/kg or greater in rats. Intravenous administration to dogs caused transient ataxia, pale gums, pupil dilation, tremors, elevated heart rate, and depressed blood pressure.

Magnesium stearate (557-04-0)
LD50 Oral Rat > 2000 mg/kg

Sodium lauryl sulfate (151-21-3)
LD50 Oral Rat 1288 mg/kg
LD50 Dermal Rabbit 580 mg/kg
LC50 Inhalation Rat > 3900 mg/m³ (Exposure time: 1 h)

Skin Corrosion/Irritation: Not classified
Erlotinib (183321-74-6)
Additional information Minimal skin irritation was seen in rabbits.

Serious Eye Damage/Irritation: Not classified
Erlotinib (183321-74-6)
Additional information: When the eyes of rabbits were treated with erlotinib, there was a clear discharge, slight conjunctival reddening and chemosis.

Respiratory or Skin Sensitization: May cause an allergic skin reaction.
Erlotinib (183321-74-6)
Additional information: In the guinea pig maximization test, erlotinib was considered a mild skin sensitizer.

Germ Cell Mutagenicity: Not classified
Erlotinib (183321-74-6)
Additional information: Erlotinib did not have genotoxicity in a series of in vitro assays (bacterial mutation, human lymphocyte chromosome aberration, and mammalian cell mutation) and an in vivo mouse bone marrow micronucleus test.

Carcinogenicity: Not classified
Erlotinib (183321-74-6)
Additional information: Erlotinib was negative for carcinogenicity following 2 years of oral administration to rats and mice.

Reproductive Toxicity: Suspected of damaging the unborn child.
Erlotinib (183321-74-6)
Additional information: No teratogenic effects were observed in rabbits or rats. Erlotinib has been shown to cause embryo/fetal lethality associated with maternal toxicity and abortion in rabbits when given at doses that result in plasma drug concentrations of approximately 3 times those in humans (AUCs at 150 mg daily dose). When given to achieve plasma drug concentrations approximately equal to those in humans, there was no increased incidence of embryo/fetal lethality or abortion in rabbits or

rats. However, female rats treated with 30 mg/m²/day or 60 mg/m²/day (0.3 or 0.7 times the clinical dose, on a mg/m² basis) of erlotinib prior to mating through the first week of pregnancy had an increase in early resorptions which resulted in a decrease in the number of live fetuses. Erlotinib did not impair fertility in either male or female rats at doses up to 60 mg/m²/day.

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): May cause damage to organs through prolonged or repeated exposure.

Erlotinib (183321-74-6)

Additional information: Repeat oral toxicity studies up to 6 months and 12 months have been conducted in rats and dogs, respectively. Effects in rats treated with 30 mg/m²/day or 60 mg/m²/day (0.3 or 0.7 times the clinical dose, on a mg/m² basis) of erlotinib included decreased food consumption and body weight gain, increases in total bilirubin, and marginal increases in alanine aminotransferase (ALT), ovarian atrophy, renal papillary necrosis with tubular dilatation, multifocal necrosis, angiectasis of the adrenal gland, and follicular degeneration/inflammation of the skin. In dogs, a decrease in body weight at 150 mg/m²/day or greater, reddening of the skin, and buccal mucus membrane at 50 mg/m²/day or greater were seen.

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: If tablet is crushed: May cause respiratory irritation.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: If tablet is crushed: Causes eye irritation.

Symptoms/Injuries After Ingestion: May be harmful if swallowed.

Chronic Symptoms: Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.

12. ECOLOGICAL INFORMATION

Toxicity

Sodium lauryl sulfate (151-21-3)

LC50 Fish 1: 8 (8 - 12.5) mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])

EC50 Daphnia 1: 1.8 mg/l (Exposure time: 48 h - Species: Daphnia magna)

LC 50 Fish 2: 15 (15 - 18.9) mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])

Persistence and Degradability: No additional information available.

Bioaccumulative Potential

Sodium lauryl sulfate (151-21-3)

BCF fish 1: (will not bioconcentrate)

Log Pow: 1.6

Mobility in Soil: No additional information available.

Other Adverse Effects

No additional information available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Waste Disposal Recommendations: Dispose of contents and container according to local, regional, national, and international regulations.

Ecology – Waste Materials: Avoid release to the environment.

14. TRANSPORT INFORMATION

In Accordance with DOT Not regulated for transport.

In Accordance with IMDG Not regulated for transport.



Innovating for
affordable healthcare

In Accordance with IATA Not regulated for transport.

15. REGULATORY INFORMATION

US Federal Regulations Not applicable

US State Regulations Not applicable

16. OTHER INFORMATION

Revision date: 05 Dec. 2019

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