SAFETY DATA SHEET

Section 1: Identification	
Material **Recommended use**	Erlotinib Tablets 25 mg, 100 mg & 150 mg Pharmaceutical product used as Antineoplastic
Manufacturer	Hetero Labs Limited Unit V, Survey. No 439, 440, 441 & 458, Polepally Village, Mahabubnagar, Telangana 509301 India
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Classification of the Substance or Mixture **GHS - Classification** **Health Hazards:**	Acute toxicity (Category 4) Harmful if swallowed.
Label Elements **Signal Word: Warning** **Precautionary Statements:**	Do not breathe dust IF exposed or you feel unwell: Call a POISON CENTER or doctor/physician.
Other Hazards	Note - no information available
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Erlotinib Hydrochloride	183319-69-9
Microcrystalline Cellulose	9004-34-6
Lactose Monohydrate	10039-26-6
Sodium Starch glycolate	9063-38-1
Sodium lauryl Sulfate	151-21-3
Magnesium Stearate	557-04-0
Opadry white	NA

Section 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 Contac	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).	

Section 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.
Section 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.

Section 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.
Section 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.
Section 9: Physical and Chemical Properties	
Physical Form	Solid
Appearance	Erlotinib tablets, 25 mg: White colored, round biconvex film-coated tablets debossed with "H" on one side and "28" on the other side. They are supplied in: Bottle of 30 tablets NDC 31722-263-30 Erlotinib tablets, 100 mg: White colored, round biconvex film-coated tablets debossed with "H" on one side and "21" on the other side. They are supplied in: Bottle of 30 tablets NDC 31722-264-30 Erlotinib tablets, 150 mg: White colored, round biconvex film-coated tablets debossed with "H" on one side and "22" on the other side. They are supplied in: Bottle of 30 tablets NDC 31722-265-30
Section 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, CO2). Nitrogen oxides. Hydrogen chloride gas.
Section 11: Toxicological Information	
Acute Toxicity:	Not classified

Erlotinib **Minimum Lethal Dose Oral Rat** **Minimum Lethal Dose Oral Mouse** **Minimum Lethal Dose Oral Dog** **Minimum Lethal Dose Intravenous Rat** **Minimum Lethal Dose Intravenous Mouse** **Minimum Lethal Dose Intravenous Dog**	 1000 mg/kg 2000 mg/kg > 200 mg/kg 50 mg/kg 75 mg/kg > 15 mg/kg
Additional information	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 **LD50 Oral Rat**	 > 2000 mg/kg
Sodium lauryl sulfate **LD50 Oral Rat** **LD50 Dermal Rabbit** **LC50 Inhalation Rat**	 1288 mg/kg 580 mg/kg > 3900 mg/m³
Skin Corrosion/Irritation:	Not classified
Erlotinib **Additional information**	 Minimal skin irritation was seen in rabbits.
Serious Eye Damage/Irritation:	Not classified
Erlotinib **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 **Additional information:**	In the guinea pig maximization test, erlotinib was considered a mild skin sensitizer.
Germ Cell Mutagenicity:	Not classified
Erlotinib **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 **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 **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 **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.
Section 12: Ecological Information	
Toxicity Sodium lauryl sulfate	
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.
Mobility in Soil: No additional information available.	
Other Adverse Effects No additional information available	

Section 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.
Section 14: Transport Information	
In Accordance with DOT	Not regulated for transport.
In Accordance with IATA	Not regulated for transport.
In Accordance with IMDG	Not regulated for transport.
Section 15: Regulatory Information	
US Federal Regulations	Not applicable
US State Regulations	Not applicable

Section 16: Other Information

Issue Date : 13-06-2024

Version: 00

Further information

Revision date: New issue

Revision note: New issue

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