



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification	
Material	Cinacalcet Tablets, 30 mg, 60 mg and 90 mg
Manufacturer	Hetero Labs Limited Unit-III, 22-110, IDA, Jeedimetla, Hyderabad, India
Distributor	Camber Pharmaceuticals, Inc. , Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
Classification	Material may be irritating to the mucous membranes and upper respiratory tract. May be harmful by inhalation, ingestion, or skin absorption. May cause an allergic skin reaction. May cause damage to {cecum and eyes} through prolonged or repeated exposure. May cause eye, skin, or respiratory system irritation. Very toxic to aquatic life with long lasting effects. To the best of our knowledge, the toxicological properties have not been thoroughly investigated.
Environment	No information available
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Cinacalcet HCl	364782-34-3
Section 4: First-Aid Measures	
Ingestion	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician.
Inhalation	Move to fresh air. If symptoms persist, call a physician.
Skin Contact	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary.
Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Notes to Physician:	Treat symptomatically.
Section 5: Fire-Fighting Measures	
Flammable Properties:	No information available.
Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment and Precautions for Firefighters	As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH (approved) and full protective gear.
Other information	No information available.



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Section 6: Accidental Release Measures

Personal Precautions

If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment in cleaning up a spill. If in powder form, wet down spilled material to minimize airborne dispersion. Soak up material with absorbent e.g., paper towels, and wash spill area thoroughly with appropriate cleaning materials. Dispose of collected material in accordance with applicable waste disposal regulations. Avoid release to the environment.

Environmental Precautions

Take steps to avoid release into the environment, if safe to do so.

Clean-up Methods

Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.

Section 7: Handling and Storage

Handling

Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke in work areas. Use adequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material. Remove contaminated clothing prior to entering eating areas. Clean protective equipment thoroughly after each use. Store in a well ventilated area.

Storage

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Section 8: Exposure Controls/Personal Protection

Eye/face Protection:

Wear safety glasses with side shields, chemical splash goggles, or safety glasses with side shields and a full-face shield to prevent contact with eyes. The choice of protection should be based on the job activity and potential for exposure to the eyes and face

Skin Protection:

Use gloves or other appropriate personal protective equipment if skin contact with formulation is possible. Wear lab coat or other protective over garment if splashing is possible. The choice of protection should be based on the job activity and potential for skin contact.

Respiratory Protection:

When possible, handle material in enclosed processes or containers. If it is properly handled with effective local exhaust ventilation or containment, respiratory protection may not be needed. For procedures involving larger quantities or dust/aerosol generating procedures such as weighing or a large transfer of liquids, an air-purifying respirator with NIOSH approval for dusts and mists may be needed. The choice of protection should be based on the job activity and the potential for exposure.



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Other:

Wash hands, face and other potentially exposed areas after handling material (especially before eating, drinking or smoking). Clean protective equipment thoroughly after each use.

Section 9: Physical and Chemical Properties

Physical Form

Cinacalcet tablets, 30 mg are light green, oval, biconvex, film coated, tablets debossed with 'H' on one side and 'C6' on the other side. They are supplied as follows:

Bottles of 30 tablets NDC 31722-103-30

Carton of 30 (3x10's) unit-dose tablets NDC 31722-103-31

Cinacalcet tablets, 60 mg are light green, oval, biconvex, film coated, tablets debossed with 'H' on one side and 'C7' on the other side. They are supplied as follows:

Bottles of 30 tablets NDC 31722-104-30

Carton of 30 (3x10's) unit-dose tablets NDC 31722-104-31

Cinacalcet tablets, 90 mg are light green, oval, biconvex, film coated, tablets debossed with 'H' on one side and 'C8' on the other side. They are supplied as follows:

Bottles of 30 tablets NDC 31722-105-30

Carton of 30 (3x10's) unit-dose tablets NDC 31722-105-31

Section 10: Stability and Reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Acute Toxicity: Oral acute rat studies - LD50 >1,500 mg/kg body weight. (GHS Category - 4)

Skin corrosion/irritation: Very slight dermal irritation based on animal studies. Based on available data, the GHS classification criteria are not met.

Serious eye damage/eye irritation: Severely irritating to the eye based on animal studies. (GHS Category 1)

Respiratory or skin sensitization: Mild skin sensitization. (GHS Category 1B)

Germ cell mutagenicity: Not mutagenic in a battery of in vitro and in vivo studies. Based on available data, the GHS classification criteria are not met.

Carcinogenicity: Animal testing did not show any carcinogenic effects. Based on available data, the GHS classification criteria are not met.



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Reproductive toxicity: Not a reproductive/development toxicant in animals. Based on data, the GHS classification criteria are not met.

Aspiration Hazard: No information available

Section 12: Ecological Information

Toxicity: Avoid release into the environment.
Runoff from fire control or dilution water may cause pollution.

Section 13: Disposal Considerations

Dispose in accordance with local, state, and federal regulations.

Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Additional Information: Transport in accordance with local, state, and federal regulations.

Section 15: Regulatory Information

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances



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DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

State Regulations

California Proposition 65: This product does not contain any Proposition 65 chemicals.

Section 16: Other Information

Section 16, Other information

Issue Date : 12-10-2020

Version : 00

Further information

Revision date: NA

Revision note: NA

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.