Sensipar®
Safety Data Sheet

Revision Number: 20 **Date Issued** 17-Mar-2026

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

1.1 Product identifier

Product Name: Sensipar®
Common Name: Cinacalcet Hydrochloride (cinacalcet HCl)
Chemical Name: N-[1-(R)-(-)-(1-naphthyl)ethyl]-3-[3-(trifluoromethyl)phenyl]-1-aminopropane hydrochloride
Synonyms: Mimpara®, Cinacalcet, AMG 073

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use: Pharmaceutical
Uses advised against: No information available

Manufacturer:
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320-1799
1-805-447-7233
1-805-447-1000

Emergency Telephone Number:
Chemtrec
NORTH AMERICA 1-800-424-9300,
INTERNATIONAL 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

Pharmaceutical product intended for clinical and commercial manufacturing purposes only. Product contains an active pharmaceutical ingredient, cinacalcet, used to lower serum calcium concentrations in patients with secondary hyperparathyroidism (HPT), primary HPT, and parathyroid cancer. The most common and serious adverse effects include: hypocalcemia, upper gastrointestinal bleeding, hypotension, and a dynamic bone disease. These effects may potentially occur if exposures repeatedly exceed the Occupational Exposure Limit described below. Avoid inhalation, skin contact, eye contact, and accidental ingestion.

2.1 - Classification of the drug substance or mixture (drug product in final form, not applicable)

REGULATION (EC) No 1272/2008, WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA)

Serious Eye Damage / Eye Irritation	Category 1
Skin Sensitization	Sub-category 1B
Specific TOST - Repeated Exposure Oral	Category 2 eyes and cecum
Acute aquatic toxicity	Acute 1
Chronic aquatic toxicity	Chronic 1

2.2 Label elements

Signal Word **Danger**

SGHH0999
H302 - Harmful if swallowed
H314 - Causes severe skin burns and eye damage
H317 - May cause an allergic skin reaction
H371 - May cause damage to organs
H373 - May cause damage to organs through prolonged or repeated exposure
H410 - Very toxic to aquatic life with long lasting effects

GHSPO642
P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection
P303 + P361 + P353 - IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/ physician
P280 - Wear eye protection/ face protection
P260 - Do not breathe dust/fume/gas/mist/vapors/spray

2.3 Other Hazards
No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Ingredients: Active Ingredient - cinacalcet HCl

Chemical Name: N-[1-(R)-(-)-(1-naphthyl)ethyl]-3-[3-(trifluoromethyl)phenyl]-1-aminopropane hydrochloride
CAS-No: 364782-34-3

4. FIRST AID MEASURES

4.1 Description of first-aid measures

Eye Contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary.

Inhalation: Move to fresh air. If symptoms persist, call a physician.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician.

Notes to Physician: Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Flammable Properties: No information available.

Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Hazardous Combustion Products: No information available.

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH (approved) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Spill Procedures: 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.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling

Handling and Storage: 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: Keep containers tightly closed in a cool, well-ventilated place

Safe Handling Advice: No information available

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limit: Please refer to Section 11 for more information. No exposure guidelines established by ACGIH, NIOSH or OSHA. Amgen recommends an occupational exposure limit (OEL) of 30 µg/m^3 as an 8-hour time weighted average over a 40-hour work week. The OEL is designed as an acceptable airborne concentration of a substance for which it is believed that workers may be repeatedly exposed day after day without adverse health effects. Cinacalcet HCl has been classified per Amgen's Hazard Classification System as an Occupational Exposure Band 3 compound (20 µg/m^3 - 100 µg/m^3) with the following suffixes: SENS (sensitizer), EYE (eye damage). and Specific Target Organ Toxicity - Repeated Exposure (STOT-RE) (eye and cecum).

Engineering Controls: When practicable, handle material in enclosed processes or in processes with effective local exhaust ventilation or within a chemical hood.

8.2 Exposure controls

Personal Protective Equipment

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.

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.

8.3 Environmental exposure controls

Environmental Exposure Controls Avoid release to the environment. Please refer to Section 12 for more information.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White to off-white (cinacalcet HCl)
Physical State:	Solid
Molecular Weight:	393.87 as the HCl salt
Odor:	No information available
Odor Threshold:	No information available
pH:	5.1 (pH of aqueous solution (saturated at 25 ° C))
Melting Point:	No information available °C (cinacalcet HCl)
Boiling point	No information available
Flash Point:	No information available
Evaporation Rate:	No information available
Lower explosive limit:	No information available
Upper explosive limit:	No information available
Vapor Pressure:	No information available
Vapor Density (air = 1):	Not applicable
Relative density:	No information available
Water Solubility:	Approx. 1,500 mg/L at pH 5; <10 mg/L at pH 7
Partition Coefficient (log Kow):	Log Pow value 4.79
Viscosity:	No information available

10. STABILITY AND REACTIVITY

10.1 Reactivity No information available

10.2 Chemical stability No information available

10.3 Possibility of hazardous reactions No information available

10.4 Conditions to avoid Warning: Cinacalcet HCl, the active pharmaceutical ingredient in Sensipar, can form combustible dust concentrations in air during processing and present an explosion hazard risk. - Minimize dust generation and accumulation. Fine dust dispersed in air in sufficientconcentrations and in the presence of an ignition source is a potential dust explosion hazard. - Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. - Dry powders are sensitive to electrostatic ignition. Provide adequate precautions, such as electrical grounding, bonding, or inert atmospheres for process equipment. - Appropriately classified electrical equipment should be used. - Explosion hazards should be considered when using dust control equipment, such as local exhaust ventilation, air material separators, portable vacuums, etc. - Fire-retardant PPE maybe required for the task dependent on risk assessment. - Grounding, anti-static tools, and/or an electrically rated vacuum should be used to cleanup spills. - Refer to NFPA 652, Standard on the Fundamentals of Combustible Dust

10.5 Incompatible materials No information available

10.6 Hazardous decomposition products No information available

10.7 Other information

Dust Explosion Properties: MIE 50-100mJ, Kst Value 256 (tested on cinacalcet HCl milled granulation), MIE 50-100mJ, Kst Value 224 (tested on cinacalcet HCl final blend)

Thermal Stability: 123 ° C (tested on cinacalcet HCl milled granulation), 181 ° C (tested on cinacalcet HCl final blend)

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects Cinacalcet HCl

Acute Toxicity: Oral acute rat studies - LD50 >1,500 mg/kg body weight.
Skin corrosion/irritation: 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: Based on available data, the GHS classification criteria are not met.
Carcinogenicity: Based on available data, the GHS classification criteria are not met.
Reproductive toxicity: Not a reproductive/development toxicant, GHS classification criteria are not met.
STOT - single exposure: No information available
STOT - repeated exposure: Adverse organ effects at 10 – 100 mg/kg/day. (GHS Category 2 - eye and cecum)
Aspiration Hazard: No information available

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Ecotoxicity effects:

Cinacalcet HCl is very toxic in acute and chronic studies evaluating its effects on aquatic organisms and invertebrates.

- The 96-hour LC50 value in fathead minnow under static conditions for cinacalcet was 0.085 mg/L, with most of the mortality occurring within the first 24 hours. At the lowest concentration tested (0.063 mg/L), 1/20 or 5% of the test animals died at the 96-hour interval. No NOEC was achieved, although the 0.063 mg/L was the EC05 or LOEC for the study.

- In daphnia magna, the 24-hour and 48-hour EC50 for Cinacalcet HCl are 0.42 mg/L and 0.33 mg/L based on nominal concentrations and 0.23 and 0.16 mg/L based on measured concentrations, respectively. The NOEC was 0.11 mg/L based on nominal concentrations and 0.049 mg/L based on measured concentrations. /

- An acute algal inhibition study produced the following values:
  - 72- and 96-hr EC50 – 0.0191 and 0.0175 mg/L (cell numbers)
  - 72- and 96-hour EC50 – 0.0203 and 0.0191 mg/L (area under the growth curve)
  - 72- and 96-hour EC50 - 0.0330 and 0.0320 mg/L (growth rates)

- In a chronic daphnia reproductive study:
  - the 21-day LC50 for mortality in the parents was 0.14 mg/L
  - the LOEC and NOEC for parent mortality were 0.20 mg/L and 0.10 mg/L.
  - the LOEC and NOEC for reproductive effects were 0.050 mg/L and 0.025 mg/L, respectively.
  - the 72- and 96-hour LOEC and NOEC - 0.0250 and 0.0125 mg/L (cell numbers, area under the growth curve and growth rate).
- GHS Category Acute 1
- GHS Category Chronic 1

12.2 Persistence and degradability

Persistence/Degradability:

Cinacalcet HCl is not considered to be biodegradable based on the results of a screening respirometer test and a sealed vessel CO2 production test. An aerobic and anerobic biodegradation test in sediment suggests that if cinacalcet gets into the environment, it would irreversibly bind and remain in the sediment.

12.3 Bioaccumulative potential

Bioaccumulation/ Accumulation:

In an activated sludge respiratory inhibition study, the 3-hour EC50 and EC20 were 35.6 mg/L and 15.4 mg/L, respectively. The NOEC from the nominal concentration data and effects observed was approximately 1 mg/L.

12.4 Mobility in soil

Mobility in Environmental Media: No information available

12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment: No information available

12.6 Other adverse effects

Other Adverse Effects: No information available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste Disposal Method: Dispose of waste according to prescribed federal, state, local and competent authority guidelines.

14. TRANSPORT INFORMATION

DOT: Not regulated

IATA:

Proper Shipping Name	Environmentally Hazardous Substance, solid, n.o.s. (cinacalcet HCl)
UN-No	UN Number 3077
Packing Group	Packing Group (PG) III

IMDG/IMO:

Proper Shipping Name:	Environmentally Hazardous Substance, solid, n.o.s. (cinacalcet HCl)
UN-No.:	UN Number 3077
Packing Group:	Packing Group (PG) III
Marine Pollutant:	This product contains a chemical which is listed as a marine pollutant according to IMDG/IMO

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

TSCA:	-
EINECS/ELINCS	-
DSL/NDSL	-
PICCS:	-
ENCS:	-
CHINA:	-
AICS:	-
KECL:	-

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
DSL/NDSL - 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.

15.2 Chemical safety assessment

No CSA has been conducted.

16. OTHER INFORMATION

Revision Number: 20

To the best of our knowledge, the information provided here is accurate as of the date of the Safety Data Sheet (SDS). The information is specific to the material that is the subject of this SDS and may not be valid when this material is used in combination with any other materials or in any process. Each user should review the information provided here in the context of the user's intended manner of handling, using, processing, storing, transporting, and disposing of the material.

This information is provided without warranty or guarantee of any kind, whether express, implied or statutory, including without limitation warranty of fitness or merchantability for a particular purpose or noninfringement. No representation, warranty, or guarantee is made, and no liability is assumed, with respect to the material or the information contained in this SDS including without limitation its accuracy or completeness or the hazards of, or results obtained from, use of the material or the information contained here. Caution should be used in the handling, using, processing, storing, transporting, and disposing of the material.