



Revision Number: 6

# Parsabiv® Safety Data Sheet

Date Issued 12-Oct-2022

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

### 1.1 Product identifier

**Product Name:** Parsabiv®  
**Common Name:** Etelcalcetide HCl  
**Chemical Name:** N-Acetyl-D-cysteiny-L-(L-cysteine disulfide)-D-alanyl-D-arginyl-D-arginyl-D-arginyl-D-arginyl-D-alanyl-D-argininamide, hydrochloride salt  
**Synonyms:** AMG 416, KAI-4169

### 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 etelcalcetide HCl, an active pharmaceutical ingredient, for treatment of secondary hyperparathyroidism (sHPT) in patients with chronic kidney disease (KD) on hemodialysis. Dosage contents may pose a health hazard only if significant absorption occurs (e.g. inhalation after a major spill). Avoid inhalation, skin contact, eye contact and accidental ingestion. Based on available data, the GHS classification criteria are not met.

### 2.1 - Classification of the drug substance or mixture (drug product in final form, not applicable) REGULATION (EC) No 1272/2008

Not classified

### 2.2 Label elements

Not classified

### 2.3 Other Hazards

No information available



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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

**Ingredients:** See below

**Chemical Name:** N-Acetyl-D-cysteinyI-S-(L-cysteine disulfide)-D-alanyl-D-arginyl-D-arginyl-D-arginyl-D-alanyl-D-argininamide, hydrochloride salt

**CAS-No:** 1262780-97-1 (free base); 1334237-71-6 (hydrochloride salt)

Supplied for intravenous administration as a sterile, single-use, preservative-free liquid solution in 3 strengths: 2.5 mg etelcalcetide in 0.5 mL (5 mg/mL) solution, 5 mg etelcalcetide in 1 mL (5 mg/mL) solution, and 10 mg etelcalcetide in 2 mL (5 mg/mL) solution. All strengths are formulated with sodium hydroxide and succinic acid.

### 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:** If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

**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.



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### 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.



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### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

**Occupational Exposure Limit:** No exposure guidelines established by ACGIH, NIOSH or OSHA. Amgen recommends an occupational exposure limit (OEL) of 6 µg/m<sup>3</sup> 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. Etelcalcetide HCl has been classified per Amgen's Hazard Classification System as an Occupational Exposure Band 4 compound (5 µg/m<sup>3</sup> - 20 µg/m<sup>3</sup>).

**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.



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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	White to off-white lyophilized powder (HCl Salt and drug product) Clear, colorless liquid (liquid drug product)
<b>Molecular Weight:</b>	1 kDa
<b>Odor:</b>	No information available
<b>Odor Threshold:</b>	No information available
<b>pH:</b>	No information available
<b>Melting point (°C) VALUE</b>	No information available
<b>Flash Point:</b>	No information available
<b>Evaporation Rate:</b>	No information available
<b>Lower explosive limit:</b>	No information available
<b>Upper explosive limit:</b>	No information available
<b>Vapor Pressure:</b>	No information available
<b>Vapor Density (air = 1):</b>	No information available
<b>Relative density:</b>	No information available
<b>Water Solubility:</b>	At least 100 mg/mL (HCl salt and drug product), Fully miscible with water (liquid drug product)
<b>Partition Coefficient (log Kow):</b>	No information available
<b>Viscosity:</b>	No information available

### 10. STABILITY AND REACTIVITY

<b>10.1 Reactivity</b>	No information available
<b>10.2 Chemical stability</b>	No information available
<b>10.3 Possibility of hazardous reactions</b>	No information available
<b>10.4 Conditions to avoid</b>	No Information available
<b>10.5 Incompatible materials</b>	No information available
<b>10.6 Hazardous decomposition products</b>	No information available
<b>10.7 Other information</b>	Dust Explosion Hazard Properties tested on etelcalcetide HCl API: MIE >1000mJ MIT (dust cloud) >600° C MEC 180< MEC<225; MEC estimate 225 g/m <sup>3</sup> Kst 42 bar-m/sec ± 30% Pmax 6.1 bar ± 10%  Electrostatic Properties tested on etelcalcetide HCl API: Volume resistivity: 9.33 x 10 <sup>15</sup> Ω-cm Calculated Dielectric Constant: 1.97 Measured Decay Time: 3 sec



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### 11. TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

<b>Acute Toxicity:</b>	No information available
<b>Skin corrosion/irritation:</b>	No information available
<b>Serious eye damage/eye irritation:</b>	No information available
<b>Respiratory or skin sensitization:</b>	No information available
<b>Germ cell mutagenicity:</b>	GHS classification criteria not met. Not genotoxic based on a battery of in vitro and in vivo studies.
<b>Carcinogenicity:</b>	GHS classification criteria not met. Did not show carcinogenic effects in animal experiments
<b>Reproductive toxicity:</b>	GHS classification criteria not met. Etelcalcetide HCl did not effect developmental toxicity following intravenous exposure in rats and rabbits. Also, no reproductive/fertility toxicity has been observed in male and female rats intravenously administered etelcalcetide HCl.
<b>STOT - single exposure:</b>	Does not meet GHS Classification Criteria and therefore is not classified.
<b>STOT - repeated exposure:</b>	Does not meet GHS Classification Criteria and therefore is not classified.
<b>Aspiration Hazard:</b>	No information available

### 12. ECOLOGICAL INFORMATION

#### 12.1 Toxicity

**Ecotoxicity effects:** No information available

#### 12.2 Persistence and degradability

**Persistence/Degradability:** No information available

#### 12.3 Bioaccumulative potential

**Bioaccumulation/ Accumulation:** No information available

#### 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.



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### 14. TRANSPORT INFORMATION

**DOT:** Not regulated by U.S. DOT, IATA, or IMDG.

### 15. REGULATORY INFORMATION

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

##### International Inventories

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

##### 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.



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## 16. OTHER INFORMATION

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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.

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