1. Identification

Product identifier: Teriparatide

Other means of identification:
- Catalog number: 1643962
- CAS number: 52232-67-4
- Synonyms: Parathyroid hormone fragment 1-34 human
- Chemical name: Teriparatide
- Recommended use: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer:
- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway
  Rockville
  MD
  20852-1790
  United States
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- E-mail: RSTECH@usp.org
- Emergency phone number:
  CHEMTREC within US & Canada 1-800-424-9300
  CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards:
- Reproductive toxicity: Category 2
- Specific target organ toxicity, repeated exposure: Category 2 (bone, kidney)

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements

Signal word: Warning

Hazard statement: Suspected of damaging fertility or the unborn child. May cause damage to organs (bone, kidney) through prolonged or repeated exposure.

Precautionary statement

Prevention: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wear protective gloves/protective clothing/eye protection/face protection.

Response: If exposed or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell.

Storage: Store locked up.

Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC): None known.
Supplemental information

Highly potent pharmacologically active material.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teriparatide</td>
<td>Parathyroid hormone fragment 1-34 human</td>
<td>52232-67-4</td>
<td>100</td>
</tr>
</tbody>
</table>

4. First-aid measures

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Hypercalcemia. Highly potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>Move to fresh air. Call a physician if symptoms develop or persist.</td>
</tr>
<tr>
<td>Skin contact</td>
<td>Rinse skin with water/shower. Get medical attention if irritation develops and persists.</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Rinse with water. Get medical attention if irritation develops and persists.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.</td>
</tr>
<tr>
<td>Most important symptoms/effects, acute and delayed</td>
<td>Provide general supportive measures and treat symptomatically. Monitor serum calcium and phosphate levels. Maintain adequate hydration.</td>
</tr>
<tr>
<td>Indication of immediate medical attention and special treatment needed</td>
<td>Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.</td>
</tr>
<tr>
<td>General information</td>
<td>Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials. No unusual fire or explosion hazards noted.</td>
</tr>
</tbody>
</table>

5. Fire-fighting measures

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsuitable extinguishing media</td>
<td>None known.</td>
</tr>
<tr>
<td>Specific hazards arising from the chemical</td>
<td>No unusual fire or explosion hazards noted.</td>
</tr>
<tr>
<td>Special protective equipment and precautions for firefighters</td>
<td>Wear suitable protective equipment.</td>
</tr>
<tr>
<td>Fire fighting equipment/instructions</td>
<td>Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.</td>
</tr>
<tr>
<td>Specific methods</td>
<td>Use standard firefighting procedures and consider the hazards of other involved materials.</td>
</tr>
<tr>
<td>General fire hazards</td>
<td>No unusual fire or explosion hazards noted.</td>
</tr>
</tbody>
</table>

6. Accidental release measures

| Personal precautions, protective equipment and emergency procedures | Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS. |
| Methods and materials for containment and cleaning up | For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. |
| Environmental precautions | Avoid discharge into drains, water courses or onto the ground. |

7. Handling and storage

| Precautions for safe handling | As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity. |
| Conditions for safe storage, including any incompatibilities | None known.                                                                                     |
8. Exposure controls/personal protection

Occupational exposure limits
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

<table>
<thead>
<tr>
<th>Industrial Use</th>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Teriparate (CAS 52232-67-4)</td>
<td>TWA</td>
<td>0.009 mg/m³</td>
</tr>
</tbody>
</table>

Biological limit values
No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls
No open handling. For laboratory operations, conduct powder handling operations in an isolator or equivalent. Put powder into solution or a tightly capped container prior to removal from containment. Isolator should be equipped with bag out ports or transfer chamber. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection
Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection
Hand protection
Wear double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other
Train employees in proper gowning and degowning practices. Wear disposable laboratory coat and disposable sleeve covers appropriate to the task, two pairs of gloves, and safety glasses with side shields. An anteroom or transition area is recommended for gowning and degowning. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection
Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards
Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations
Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance
Appearance descriptions are general information and not specific to any USP lot.

Physical state
Solid.

Form
Powder.

Color
White. Off-white.

Odor
Not available.

Odor threshold
Not available.

pH
Not available.

Melting point/freezing point
Not available.

Initial boiling point and boiling range
Not available.

Flash point
Not available.

Evaporation rate
Not available.

Flammability (solid, gas)
Not available.

Upper/lower flammability or explosive limits
Flammability limit - lower (%)
Not available.

Flammability limit - upper (%)
Not available.
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Explosive limit - lower (%)</td>
<td>Not available</td>
</tr>
<tr>
<td>Explosive limit - upper (%)</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapor density</td>
<td>Not available</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Solubility (water)</td>
<td>Soluble</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not available</td>
</tr>
<tr>
<td>Other information</td>
<td></td>
</tr>
<tr>
<td>Molecular formula</td>
<td>C181H291N55O51S2</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>4117.72</td>
</tr>
</tbody>
</table>

10. Stability and reactivity

**Reactivity**

The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability**

Material is stable under normal conditions.

**Possibility of hazardous reactions**

No dangerous reaction known under conditions of normal use.

**Conditions to avoid**

Contact with incompatible materials.

**Incompatible materials**

Strong oxidizing agents.

**Hazardous decomposition products**

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. SOx.

11. Toxicological information

**Information on likely routes of exposure**

<table>
<thead>
<tr>
<th>Route</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>This material may cause: Hypercalcemia.</td>
</tr>
<tr>
<td>Skin contact</td>
<td>Knowledge about health hazard is incomplete.</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Knowledge about health hazard is incomplete.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>This material may cause: Hypercalcemia.</td>
</tr>
<tr>
<td>Symptoms related to</td>
<td>Headache. Dizziness. Leg cramps. Swelling of</td>
</tr>
<tr>
<td>the physical,</td>
<td>extremities. Urinary problems. Increase in heart</td>
</tr>
<tr>
<td>toxicological</td>
<td></td>
</tr>
<tr>
<td>characteristics</td>
<td></td>
</tr>
</tbody>
</table>

**Information on toxicological effects**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>Not known.</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Knowledge about health hazard is incomplete.</td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Knowledge about health hazard is incomplete.</td>
</tr>
<tr>
<td>Respiratory or skin sensitization</td>
<td>Knowledge about health hazard is incomplete.</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>Knowledge about health hazard is incomplete.</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>Knowledge about health hazard is incomplete.</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Knowledge about mutagenicity is incomplete.</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td></td>
</tr>
<tr>
<td>Ames test</td>
<td>Result: Negative.</td>
</tr>
<tr>
<td>Chromosome aberration</td>
<td>Result: Negative.</td>
</tr>
<tr>
<td>Micronucleus</td>
<td>Result: Negative.</td>
</tr>
<tr>
<td>Mouse lymphoma assay</td>
<td>Result: Negative.</td>
</tr>
</tbody>
</table>

Material name: Teriparatide
Carcinogenicity
Knowledge about carcinogenicity is incomplete.
0.005 - 0.075 mg/kg/day Carcinogenicity
Result: Dose-related increase in incidence of osteosarcoma.
Species: Rat
Test Duration: 2 years
Carcinogenicity
Result: Negative.
Species: Monkey
Test Duration: 18 months

IARC Monographs. Overall Evaluation of Carcinogenicity
Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)
Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens
Not listed.

Reproductive toxicity
Suspected of damaging fertility or the unborn child.
Reproductivity
0.003 mg/kg/day Reproductivity
Result: Decreased fetal survival.
Species: Rabbit
0.03 mg/kg/day Reproductivity: Subcutaneous
Result: No developmental or reproductive effects.
Species: Rat
0.225 - 1 mg/kg/day Gestational study: Subcutaneous.
Result: Increased incidence of skeletal deviations. Mild growth retardation at low dose; growth retardation and reduced motor activity in offspring at high dose.
Species: Mouse

Specific target organ toxicity - single exposure
Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure
May cause damage to organs (bone, kidney) through prolonged or repeated exposure.

Aspiration hazard
Based on available data, the classification criteria are not met.

Further information
Highly potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological information
Ecotoxicity
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
No data available.

Mobility in soil
No data available.

Other adverse effects
No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations
Disposal instructions
Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations
Dispose in accordance with all applicable regulations.

Hazardous waste code
The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products
Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information
DOT
Not regulated as dangerous goods.
IATA
Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable.

General information
It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

SARA 304 Emergency release notification
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categories
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA)
Not regulated.

US state regulations

California Proposition 65
California Proposition 65 - CRT: Listed date/Carcinogenic substance
Teriparatide (CAS 52232-67-4) Listed: August 14, 2015

International Inventories

Country(s) or region Inventory name On inventory (yes/no)*
Australia Australian Inventory of Chemical Substances (AICS) No
Canada Domestic Substances List (DSL) No
Canada Non-Domestic Substances List (NDSL) No
China Inventory of Existing Chemical Substances in China (IECSC) No
Europe European Inventory of Existing Commercial Chemical Substances (EINECS) No
Europe European List of Notified Chemical Substances (ELINCS) No
Japan Inventory of Existing and New Chemical Substances (ENCS) No
Korea Existing Chemicals List (ECL) No
New Zealand New Zealand Inventory No
Philippines Philippine Inventory of Chemicals and Chemical Substances (PICCS) No
Country(s) or region | Inventory name | On inventory (yes/no)*
--- | --- | ---
Taiwan | Taiwan Chemical Substance Inventory (TCSI) | Yes
United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

<table>
<thead>
<tr>
<th>Issue date</th>
<th>02-19-2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date</td>
<td>12-20-2018</td>
</tr>
<tr>
<td>Version #</td>
<td>05</td>
</tr>
</tbody>
</table>

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