SAFETY DATA SHEET

Revision Date: 06-07-18

According to GHS Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (Ec) No. 453/2010 and OSHA GHS Regulation

1. Identification of the substance/mixture and of the company/undertaking

Product identifier: **Parathyroid Hormone (1-34)**
Product Code: **Not Available.**
CAS No.: **99294-94-7**

Synonyms: **PTH - (1-34); Parathyroid Hormone (1-34); Teriparatide acetate**

Company: **Polypeptide Laboratories**
365 Maple Avenue
Torrance, CA 90503
Telephone: **+ 1 310-782-3569**
Toll Free: **+ 1 800 770 0557**
Fax: **+ 1 310-782-3645**
Website: **www.polypeptide.com**

2. HAZARDS IDENTIFICATION

Classification according to Regulation (EC) No. 1272/2008 [CLP]

2.1 Classification of the substance or mixture:

PTH – (1-34) is a harmful powder which may have long term effects through prolonged or repeated exposure and is also suspected of damaging the unborn child. Special caution should always be taken in the handling of biologically active material.

Acute Tox. 4 (Oral)	Repr.2	STOT RE 2
H302+H332	Harmful if swallowed or inhaled.	
H361d	Suspected of damaging the unborn child.	
H373:	May cause damage to organs through prolonged or repeated exposure.	
P260	Do not breathe dust. vapors, mist, or spray.	
P280	Wear protective gloves clothing eye protection	
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.	
P308+P313	If exposed or concerned get medical device or attention	
P330	Rinse mouth	

PTH - (1-34) is a harmful substance that may cause sensitization by inhalation and skin contact.
Special caution should always be taken in the handling of biologically active material
Wording of R-phrases and hazard statements – see section 16. Adverse physicochemical, human health and environmental effects. No additional information available.

2.2 **Label elements**:

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Warning

Content: **PTH - (1-34)**
H302: Harmful if swallowed.

H361: Suspected of damaging the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.
P201: Obtain special instructions before use
P202: Do not handle until all safety precautions have been read and understood.
P260: Do not breathe dust. vapors, mist, or spray.
P264: Wash hands, forearms, and other exposed areas thoroughly after handling.
P270: Do not eat, drink or smoke when using this product.
P280: Wear protective gloves, protective clothing, and eye protection.
P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.
P303+P313: If skin irritation or rash occurs: Get medical advice/attention.
P330: Rinse mouth

2.3. Other hazards

Other hazards: None known: Caution – substance not yet fully tested.
PBT/vPvB: The substance is not considered PBT/vPvB according to criteria in Annex XIII.

3. Composition/information on ingredients

Substances:

% w/w	Substance name	CAS-no.	EC-no.	Index-no.	REACH reg.no.
100	PTH - (1-34)	**99294-94-7**	Not Available.	Not Available.	Not Available.

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Acute Tox. 4 (Oral), H302, Repr. 2, H361 STOT RE 2, H373

Note:
Chemical Structure: C_{181}-H_{291}-N_{55}-O_{51}-S_2.x-C_2-H_4-O_2.x-H_2O

H-Ser-Val-Ser-Glu-Ile-Gln-Leu-Met-His-Asn-Leu-Gly-Lys-His-Leu-Asn-Ser-Met-Glu-Arg-Val-Glu-Trp-Leu-Arg- Lys-Lys-Leu-Gln-Asp-Val-His-Asn-Phe-OH acetate salt

4. First-aid measures

Description of first aid measures: In general: If swallowed, do not induce vomiting. Give large quantities of water to drink and get medical attention immediately. Never give anything by mouth to an unconscious person. If you feel unwell, consult a physician. Show the label where possible.

Inhalation: Move to fresh air. Call a physician if breathing becomes difficult and if symptoms persist.

Skin contact: Remove contaminated clothing. Rinse affected area with water for at least 15. Rinse skin with water/shower. Obtain medical attention if irritation develops or persists.

Eye contact: Remove contact lenses and rinse with water. Flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Get medical attention if irritation develops and persists.

Symptoms/injuries Harmful if swallowed. Suspected of damaging fertility or the unborn child. May Symptoms/injuries after inhalation Symptoms/injuries after skin contact Symptoms/injuries after eye contact Symptoms/injuries after ingestion Chronic symptoms cause damage to organs through prolonged or repeated

exposure. Prolonged exposure may cause irritation. : Prolonged exposure may cause skin irritation. : May cause slight irritation to eyes. : This material is harmful orally and can cause adverse health effects or death in significant amounts. : Suspected of damaging fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure.
Ingestion: Rinse mouth and drink plenty of water. Do not induce vomiting. If vomiting occurs keep head down to avoid vomit in the lungs. Seek medical advice immediately. Never give an unconscious person anything to drink. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed Headache. Dizziness. May cause reproductive effects. : Rinse mouth. Do NOT induce vomiting. Obtain medical attention.
Effects of exposure may include: Hyperparathyroidism, malignancy associated with hypercalcemia, vitamin D intoxication. Lowered blood pressure .
Indication of any immediate medical attention and special treatment needed:
Show this safety data sheet to a physician or emergency ward.

5. Fire-fighting measures

Extinguishing Media:
Carbon dioxide, dry chemical powder or appropriate foam. Water spray.
Special fire fighting procedures:
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Unusual fire and explosions hazards:
Emits toxic fumes under fire conditions.

6. Accidental release measures

General measures: Do not get in eyes, on skin, or on clothing. Do not breathe dust. Avoid all contact with skin, eyes, or clothing.

Emergency procedures: Ventilate area. 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 permi
Protective equipment Emergency procedures: Use appropriate personal protection equipment (PPE) - see section 8. Limit generation of dust. Keep unauthorized persons away. Evacuate unnecessary personnel. Wear full face respirator, chemical safety goggles, rubber boots and heavy rubber gloves.
For containment: Contain spillage; prevent further leakage if safe to do so. Do not let product enter drains. Sweep up the spill and collect in a bag for disposal according to local, state and federal regulations. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete.

Methods for containment and cleaning up: Clean up spills immediately and dispose of waste safely. Recover the product by vacuuming, shoveling or sweeping. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

7. Handling and storage

Precautions for safe handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Handle empty containers with care because they may still present a hazard. Do not get in eyes, on skin, or on clothing. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do NOT breathe dust. Avoid contact with skin, eyes and clothing.

Storage conditions: Store in tightly closed container below –20°C (freezer storage) in a dry place .Protected from light. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product. Keep tightly closed. Store in a cool dry place.

8. Exposure controls/Personal protection

Control parameters:	No additional information available
Exposure controls:	
Appropriate engineering controls:	Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.
Personal protective equipment espiratory protection.	Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear
Materials for protective clothing:	Chemically resistant materials and fabrics.
Hand protection:	Wear protective gloves.
Eye protection:	Chemical safety goggles.
Skin and body protection:	Wear suitable protective clothing.
Respiratory Protrecton:	If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.
Other Information:	When using, do not eat, drink or smoke. EN (English) 3

Wear appropriate NIOSH / MSHA-approved respirator, chemical-resistant gloves, safety goggles, other protective clothing. Use only in a chemical fume hood. Safety shower and eye wash station.
Wash thoroughly after handling. Hygiene Measures: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of the day.

9. Physical and chemical properties

Appearance:	Solid powder.
Odor:	Not determined.
Mol. Wt.:	4117.8
pH (aqueous solution of 1 %):	Not determined.
Melting point/freezing point (◦C):	Not determined.
Initial boiling point and boiling range (◦C):	Not determined
Flash point (◦C):	Not determined
Evaporation rate:	Not determined
Flammability (solid, gas):	Not determined
Upper/lower flammability or explosive limits(vol-%):	Not determined
Vapor pressure:	Not determined
Relative density:	Not determined
Solubility:	Soluble in 1% acetic acid at 1 mg/mL to a clear, colorless solution
Partition coefficient: n-octanol/water:	Not determined
Auto-ignition (◦C):	Not determined
Decomposition temperature (◦C):	Not determined
Viscosity:	Not relevant
Explosive/oxidizing properties:	Not relevant
Purity :	≥98.5%

Other information:
None relevant.

10. STABILITY AND REACTIVITY

Reactivity:
No available information.
Chemical stability:
Stable under normal conditions. Combustible.
Possibility of hazardous reactions:
No known.
Conditions to avoid:
Strong heat, light and moisture.
Incompatible materials:
No known.
Hazardous decomposition products:
Combustion may produce oxides of carbon, nitrogen.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects Acute toxicity : Oral: Harmful if swallowed. Information on toxicological effects:

No toxicological data available. Caution - substance not yet fully tested.
Information on likely routes of exposure: Inhalation, skin and ingestion.
Symptoms:
No toxicological data available.
Inhalation: May be harmful if inhaled. Symptoms may include irritation of mucous membranes and upper respiratory tract.
Skin: May cause irritation. May be harmful if absorbed through the skin.
Eyes: May cause irritation.
Ingestion: May be harmful.
Eyes: May cause irritation.
Ingestion: May be harmful.
Chronic effects: Hyperparathyroidism, malignancy associated with hypercalcemia, vitamin D intoxication. Lowered blood pressure. May cause allergic reactions in susceptible individuals by skin contact or by inhalation. Suspected of damaging the unborn child.

12. ECOLOGICAL INFORMATION

Toxicity:
Ecology – general: No data available.
Persistence and degradability:
No data available.
Bioaccumulative potential:
No data available.
Mobility in soil:
No data available.
Results of PBT and vPvB assessment:
The substance is not considered PBT/vPvB according to criteria in Annex XIII.
Other adverse effects:
Avoid release to the environment. The environmental effects of the compound are sparsely described in literature.

13. DISPOSAL CONSIDERATIONS

Waste disposal recommendations: Disposal of contents/container should be according to Local, State, Regional, National and International Environmental Regulations. Dispose of through authorized facilities or pass on to chemical disposal company that can dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. (EWC-code:07 05 99.
Additional information: Container may remain hazardous when empty. Continue to observe all precautions.
Ecology - waste materials: Avoid release to the environment.

14. TRANSPORT INFORMATION

DOT (US): Shipped under ambient temperature as non-hazardous chemical.

UN-no.:	UN proper shipping name:	Transport hazard class(es):	Packing group:
Not Available.	Not Available.	Not Available.	Not Available.

Environmental hazards: None.
Special precautions for user: None.
Overland transport: No additional information available
Transport by sea: No additional information available
Air transport: No additional information available
Transport in bulk according to Annex II of MARPOL and the IBC Code: Not Available.

15. REGULATORY INFORMATION

US Classification and Label Text
Safety, health and environmental regulations/legislation specific for the substance or mixture
Must not be used by persons under 18 years of age. The employer shall assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions (Directive 92/85/EEC).

Chemical safety assessment :No CSR.

16. OTHER INFORMATION

The information presented herein is believed to be accurate and representative of currently accepted technical literature. However, PolyPeptide Laboratories does not mean to imply its completeness or comprehensiveness. Therefore, we suggest the use of this information solely as a guide in the use and handling of this product, and further urge the user to determine the suitability of this material for any particular purpose. PolyPeptide Laboratories shall not be held liable for any damages resulting from sole reliance on this information.

Revision date:	**06-07-18**
Data sources:	**According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EC) No. 453/2010 EU GHS SDS : 24/09/2015 :**

Full text of H-and EUH-statements:

Acute Tox. 4 (Oral)	**Acute toxicity (oral), Category 4**
Repr.2	**Reproductive toxicity, Category 2**
STOT RE 2	**Specific target organ toxicity - Repeated exposurel Category 2**
H302	**Harmful if swallowed**
H361	**Suspected of damaging fertility or the unborn child.**
H373	**May cause damage to organs through prolonged or repeated exposure**

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Hazard statements mentioned in section 2 and 3: H302+H332: Harmful if swallowed or if inhaled. H361d: Suspected of damaging the unborn child. H373: May cause damage to organs through prolonged or repeated exposure. Abbreviations: CMR = Carcinogenicity, mutagenicity and reproductive toxicity CSR = Chemical Safety Report DNEL = Derived No-Effect Level PBT = Persistent, Bioaccumulative, Toxic PNEC = Predicted No-Effect Concentration vPvB = very Persistent, very Bioaccumulative

Abbreviations:

CMR = Carcinogenicity, mutagenicity and reproductive toxicity
CSR = Chemical Safety Report
DNEL = Derived No-Effect Level
LD_{50} = Lethal Dose 50 %
PBT = Persistent, Bioaccumulative, Toxic
PNEC = Predicted No-Effect Concentration
vPvB = very Persistent, very Bioaccumulative

Literature:

Training advice:

No special training is required. However, the user should be well instructed in the execution of his/her task, be familiar with this Safety Data Sheet and have normal training in the use of personal protective equipment.

NFPA(US): H - 1 F - ND S - ND O - ND
ND - Not Determined.

Additional information:

PTH acts to increase the concentration of calcium in the blood by acting upon the parathyroid hormone receptors. Parathyroid hormone is the most important endocrine regulator of calcium and phosphorus concentration in extracellular fluid. This hormone is secreted from cells of the parathyroid glands and finds its major target cells in bone and kidney. Parathyroid hormone accomplishes its job by stimulating at least three processes: mobilization of calcium from bone, enhancing absorption of calcium from the small intestine, suppression of calcium loss in urine. PTH (1-34) is a peptide fragment (34 amino acids) of the naturally occurring human parathyroid hormone, which is an important regulator of calcium and phosphorus metabolism. The classification in Section 2 is based on the information provided by the manufacturer. The SDS is prepared based on the information available to Altox A/S as of October 6th 2015.

Changes since the previous edition: Section 1