Calcitonin Salmon Injection, Synthetic USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Date of Issue: 11/11/2021 Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Calcitonin Salmon Injection, Synthetic USP

1.2. Intended Use of the Product

Pharmaceutical injectable for the treament of osteoporosis, the treatment of Paget's Disease, and for reducing blood calcium levels.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Par Sterile Products, LLC
870 Parkdale Rd
Rochester, MI 48307
800-828-9393 Medical Affairs
drugsafety@parpharm.com

1.4. Emergency Telephone Number

Emergency Number : For Chemical Emergency, Spill, Leak, Fire, Exposure, or Accident, call CHEMTREC – Day or Night
Within USA and Canada: 1-800-424-9300 or +1-703-527-3887 (collect calls accepted)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Not classified

2.2. Label Elements

GHS-US/CA Labeling

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Phenol	Hydroxybenzene / Monohydroxybenzene / Phenic acid / Benzene, hydroxy- / Carbolic acid	(CAS-No.) 108-95-2	0.5	Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation:dust,mist), H331 Skin Corr. 1B, H314 Eye Dam. 1, H318 Muta. 2, H341 STOT SE 1, H370 STOT RE 2, H373 Aquatic Acute 2, H401 Aquatic Chronic 2, H411
Acetic acid	Acetic acid, glacial / Ethanoic acid / Ethylic acid / Vinegar acid / ACETIC ACID / Acetic acid solution / Acetic acid ...% / acetic acid	(CAS-No.) 64-19-7	0.225	Flam. Liq. 3, H226 Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402
Calcitonin (salmon)	Salcatonin / Calcitonin / Calcitonin Salmon Injection, Synthetic USP / Calcitonin Salmon Injection, Synthetic USP	(CAS-No.) 47931-85-1	0.0033	Acute Tox. 3 (Oral), H301

Full text of H-statements: see section 16

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Wash with plenty of soap and water. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Not expected to present a significant hazard under anticipated conditions of normal use.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Not flammable. Use extinguishing media suitable for surrounding type of fire.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: None expected under normal conditions of use.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

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 permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material, then place in suitable container. Contact competent authorities after a large spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Pharmaceutical injectable for the treament of osteoporosis, the treatment of Paget's Disease, and for reducing blood calcium levels.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Phenol (108-95-2)		
USA ACGIH	ACGIH OEL TWA [ppm]	5 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen,Skin - potential significant contribution to overall exposure by the cutaneous route
USA ACGIH	BEI (BLV)	250 mg/g Kreatinin Parameter: Phenol with hydrolysis - Medium: urine - Sampling time: end of shift (background, nonspecific)
USA OSHA	OSHA PEL (TWA) [1]	19 mg/m³
USA OSHA	OSHA PEL (TWA) [2]	5 ppm
USA OSHA	Limit value category (OSHA)	prevent or reduce skin absorption
USA NIOSH	NIOSH REL (TWA)	19 mg/m³
USA NIOSH	NIOSH REL TWA [ppm]	5 ppm
USA NIOSH	NIOSH REL (Ceiling)	60 mg/m³
USA NIOSH	NIOSH REL C [ppm]	15.6 ppm
USA IDLH	IDLH [ppm]	250 ppm
Alberta	OEL TWA	19 mg/m³
Alberta	OEL TWA [ppm]	5 ppm
British Columbia	OEL TWA [ppm]	5 ppm
Manitoba	OEL TWA [ppm]	5 ppm
New Brunswick	OEL TWA	19 mg/m³
New Brunswick	OEL TWA [ppm]	5 ppm
Newfoundland & Labrador	OEL TWA [ppm]	5 ppm
Nova Scotia	OEL TWA [ppm]	5 ppm
Nunavut	OEL STEL [ppm]	7.5 ppm
Nunavut	OEL TWA [ppm]	5 ppm
Northwest Territories	OEL STEL [ppm]	7.5 ppm
Northwest Territories	OEL TWA [ppm]	5 ppm

Ontario	OEL TWA [ppm]	5 ppm
Prince Edward Island	OEL TWA [ppm]	5 ppm
Québec	VEMP (OEL TWA)	19 mg/m³
Québec	VEMP (OEL TWA) [ppm]	5 ppm
Saskatchewan	OEL STEL [ppm]	7.5 ppm
Saskatchewan	OEL TWA [ppm]	5 ppm
Yukon	OEL STEL	38 mg/m³
Yukon	OEL STEL [ppm]	10 ppm
Yukon	OEL TWA	19 mg/m³
Yukon	OEL TWA [ppm]	5 ppm

Acetic acid (64-19-7)		
USA ACGIH	ACGIH OEL TWA [ppm]	10 ppm
USA ACGIH	ACGIH OEL STEL [ppm]	15 ppm
USA OSHA	OSHA PEL (TWA) [1]	25 mg/m³
USA OSHA	OSHA PEL (TWA) [2]	10 ppm
USA NIOSH	NIOSH REL (TWA)	25 mg/m³
USA NIOSH	NIOSH REL TWA [ppm]	10 ppm
USA NIOSH	NIOSH REL (STEL)	37 mg/m³
USA NIOSH	NIOSH REL STEL [ppm]	15 ppm
USA IDLH	IDLH [ppm]	50 ppm
Alberta	OEL STEL	37 mg/m³
Alberta	OEL STEL [ppm]	15 ppm
Alberta	OEL TWA	25 mg/m³
Alberta	OEL TWA [ppm]	10 ppm
British Columbia	OEL STEL [ppm]	15 ppm
British Columbia	OEL TWA [ppm]	10 ppm
Manitoba	OEL STEL [ppm]	15 ppm
Manitoba	OEL TWA [ppm]	10 ppm
New Brunswick	OEL STEL	37 mg/m³
New Brunswick	OEL STEL [ppm]	15 ppm
New Brunswick	OEL TWA	25 mg/m³
New Brunswick	OEL TWA [ppm]	10 ppm
Newfoundland & Labrador	OEL STEL [ppm]	15 ppm
Newfoundland & Labrador	OEL TWA [ppm]	10 ppm
Nova Scotia	OEL STEL [ppm]	15 ppm
Nova Scotia	OEL TWA [ppm]	10 ppm
Nunavut	OEL STEL [ppm]	15 ppm
Nunavut	OEL TWA [ppm]	10 ppm
Northwest Territories	OEL STEL [ppm]	15 ppm
Northwest Territories	OEL TWA [ppm]	10 ppm
Ontario	OEL STEL [ppm]	15 ppm
Ontario	OEL TWA [ppm]	10 ppm
Prince Edward Island	OEL STEL [ppm]	15 ppm
Prince Edward Island	OEL TWA [ppm]	10 ppm
Québec	VECD (OEL STEL)	37 mg/m³
Québec	VECD (OEL STEL) [ppm]	15 ppm
Québec	VEMP (OEL TWA)	25 mg/m³
Québec	VEMP (OEL TWA) [ppm]	10 ppm
Saskatchewan	OEL STEL [ppm]	15 ppm
Saskatchewan	OEL TWA [ppm]	10 ppm
Yukon	OEL STEL	43 mg/m³

Yukon	OEL STEL [ppm]	25 ppm
Yukon	OEL TWA	25 mg/m³
Yukon	OEL TWA [ppm]	10 ppm

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles.

Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: 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.

Environmental Exposure Controls: Avoid unnecessary release into the environment.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	:	Liquid
Appearance	:	Clear liquid
Odor	:	Not determined
Odor Threshold	:	No data available
pH	:	3.9 – 4.5
Evaporation Rate	:	No data available
Melting Point	:	No data available
Freezing Point	:	No data available
Boiling Point	:	No data available
Flash Point	:	No data available
Auto-ignition Temperature	:	No data available
Decomposition Temperature	:	No data available
Flammability (solid, gas)	:	Not applicable
Lower Flammable Limit	:	No data available
Upper Flammable Limit	:	No data available
Vapor Pressure	:	No data available
Relative Vapor Density at 20°C	:	No data available
Relative Density	:	No data available
Specific Gravity	:	No data available
Solubility	:	Fully miscible.
Partition Coefficient: N-Octanol/Water	:	No data available
Viscosity	:	No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products:

None expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Not classified (Based on available data, the classification criteria are not met)

Acute Toxicity (Dermal): Not classified (Based on available data, the classification criteria are not met)

Acute Toxicity (Inhalation): Not classified (Based on available data, the classification criteria are not met)

LD50 and LC50 Data:

No additional information available

Skin Corrosion/Irritation: Not classified (Based on available data, the classification criteria are not met)

pH: 3.9 – 4.5

Eye Damage/Irritation: Not classified (Based on available data, the classification criteria are not met)

pH: 3.9 – 4.5

Respiratory or Skin Sensitization: Not classified (Based on available data, the classification criteria are not met)

Germ Cell Mutagenicity: Not classified (Based on available data, the classification criteria are not met)

Carcinogenicity: Not classified (Based on available data, the classification criteria are not met)

Specific Target Organ Toxicity (Repeated Exposure): Not classified (Based on available data, the classification criteria are not met)

Reproductive Toxicity: Not classified (Based on available data, the classification criteria are not met)

Specific Target Organ Toxicity (Single Exposure): Not classified (Based on available data, the classification criteria are not met)

Aspiration Hazard: Not classified (Based on available data, the classification criteria are not met)

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Calcitonin (salmon) (47931-85-1)	
LD50 Oral Rat	> 72800 µg/kg
ATE US/CA (oral)	100.00 mg/kg body weight

Phenol (108-95-2)	
LD50 Oral Rat	340 mg/kg
LD50 Dermal Rabbit	630 mg/kg
ATE US/CA (dust, mist)	0.50 mg/l/4h

Acetic acid (64-19-7)	
LD50 Oral Rat	3310 mg/kg

Phenol (108-95-2)	
IARC Group	3
National Toxicology Program (NTP) Status	Twelfth Report - Items under consideration.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Phenol (108-95-2)	
LC50 Fish 1	11.9 – 50.5 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
EC50 - Crustacea [1]	4.24 – 10.7 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 Fish 2	20.5 – 25.6 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [2]	10.2 – 15.5 mg/l (Exposure time: 48 h - Species: Daphnia magna)
NOEC Chronic Fish	0.75 mg/l

Acetic acid (64-19-7)

LC50 Fish 1	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [1]	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 Fish 2	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

12.2. Persistence and Degradability

Calcitonin Salmon Injection, Synthetic USP	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Calcitonin Salmon Injection, Synthetic USP	
Bioaccumulative Potential	Not established.

Phenol (108-95-2)	
BCF Fish 1	(no significant bioaccumulation)
Partition coefficient n-octanol/water (Log Pow)	1.5

Acetic acid (64-19-7)	
Partition coefficient n-octanol/water (Log Pow)	-0.31 (at 20 °C)

12.4. Mobility in Soil

Calcitonin Salmon Injection, Synthetic USP	
Ecology - Soil	Leaches if exposed to water.

12.5. Other Adverse Effects

Other Adverse Effects: None known.

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Treatment Methods: Incineration is the preferred method for disposal of waste product. Can be landfilled, when in compliance with local regulations.

Sewage Disposal Recommendations: Do not dispose of waste into sewer.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Additional Information: Disposal through controlled incineration or authorized waste dump.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

14.4. In Accordance with TDG

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Phenol (108-95-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active Listed on the United States SARA Section 302 Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	1000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 – 10000 lb
SARA Section 313 - Emission Reporting	1 %

Acetic acid (64-19-7)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
CERCLA RQ	5000 lb

15.2. US State Regulations

Calcitonin Salmon Injection, Synthetic USP
State or local regulations

Phenol (108-95-2)
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

Acetic acid (64-19-7)
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

15.3. Canadian Regulations

Phenol (108-95-2)
Listed on the Canadian DSL (Domestic Substances List)

Acetic acid (64-19-7)
Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 11/11/2021

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

GHS Full Text Phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Flam. Liq. 3	Flammable liquids Category 3
Met. Corr. 1	Corrosive to metals Category 1
Muta. 2	Germ cell mutagenicity Category 2
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Corr. 1B	Skin corrosion/irritation Category 1B
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
STOT SE 1	Specific target organ toxicity (single exposure) Category 1
H226	Flammable liquid and vapor
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed

H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H331	Toxic if inhaled
H341	Suspected of causing genetic defects
H370	Causes damage to organs
H373	May cause damage to organs through prolonged or repeated exposure
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H411	Toxic to aquatic life with long lasting effects

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.

NA GHS SDS 2015 (Can, US)