1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Material Name: Calcitonin Salmon Solution for Injection

Trade Name: Ostosalm Solution

Chemical Family: Mixture

Intended Use: Pharmaceutical product for the treatment of osteoporosis, Paget's disease of bone, hypercalcaemia

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcitonin Salmon</td>
<td>47931-85-1</td>
<td>256-342-8</td>
<td>50 or 100 IU/mL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>*</td>
</tr>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>200-580-7</td>
<td>*</td>
</tr>
<tr>
<td>Sodium acetate</td>
<td>127-09-3</td>
<td>204-823-8</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Clear, colorless solution

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

Short Term: Not expected to cause skin irritation. Acute toxicity following ingestion is not expected.

Known Clinical Effects: Adverse effects reported in clinical trials include headache, paraesthesia (tingling or itching), nausea, and diarrhea. Serious allergic reactions, including anaphylaxis, have been reported.

EU Indication of danger: Not classified

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.
4. FIRST AID MEASURES

Eye Contact: Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.

Ingestion: Get medical attention. Wash out mouth with water.

Inhalation: Move to fresh air. Get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not determined

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Storage Conditions: Protect from light. Store at controlled room temperature.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Acetic acid

<table>
<thead>
<tr>
<th>Source</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>10 ppm TWA</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³ TWA</td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 ppm TWA</td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (STEL)</td>
<td>15 ppm STEL</td>
</tr>
<tr>
<td>Australia STEL</td>
<td>15 ppm STEL</td>
</tr>
<tr>
<td></td>
<td>37 mg/m³ STEL</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 ppm TWA</td>
</tr>
<tr>
<td></td>
<td>25 mg/m³ TWA</td>
</tr>
</tbody>
</table>
The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

**Engineering Controls:**
Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

**Personal Protective Equipment:**

- **Hands:** Wear protective gloves when working with large quantities.
- **Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
- **Skin:** Wear protective clothing when working with large quantities.
- **Respiratory protection:** Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Liquid solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>Colorless</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

### 10. STABILITY AND REACTIVITY

- **Stability:** Stable under normal conditions of use.
- **Conditions to Avoid:** Not determined
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.

### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

**Acute Toxicity: (Species, Route, End Point, Dose)**

- **Calcitonin Salmon**
  - Rat Oral Minimum Lethal Dose > 400 mg/kg

- **Sodium chloride**
  - Rat Oral LD50 3000 mg/kg
  - Mouse Oral LD50 4000 mg/kg

- **Acetic acid**
  - Rat Oral LD50 3530 mg/kg
  - Mouse Inhalation LC50 5000 ppm

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

**Irritation / Sensitization: (Study Type, Species, Severity)**

- **Sodium chloride**
  - Eye Irritation Rabbit Moderate
  - Skin Irritation Rabbit Mild
Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Calcitonin Salmon
4 Week(s) Rat Oral 40 ug/kg NOAEL None identified
4 Week(s) Dog Oral 2000 µg/day NOAEL None identified

Sodium chloride
10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Calcitonin Salmon
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
Bacterial Mutagenicity (Ames) Salmonella , E. coli Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Calcitonin Salmon
1 Year(s) Rat 20 IU/kg/day LOEL Benign tumors, Pituitary gland

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Acetic acid
Fathead minnow LC-50 1 Hours > 315 mg/L
Fathead minnow LC-50 24 Hours 122 mg/L
Mysid Shrimp LC-50 48 Hours 100-300 mg/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Calcitonin Salmon
   Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
   EU EINECS List 256-342-8

Sodium chloride
   Inventory - United States TSCA - Sect. 8(b): Present
   Australia (AICS): Present
   EU EINECS List 231-598-3

Acetic acid
   CERCLA/SARA Hazardous Substances and their Reportable Quantities: = 2270 kg final RQ = 5000 lb final RQ
   Inventory - United States TSCA - Sect. 8(b): Present
   Australia (AICS): Present
   Standard for the Uniform Scheduling for Drugs and Poisons:
     Schedule 2
     Schedule 5
     Schedule 6
   EU EINECS List 200-580-7

Sodium acetate
   Inventory - United States TSCA - Sect. 8(b): Present
   Australia (AICS): Present
   EU EINECS List 204-823-8

16. OTHER INFORMATION

Reasons for Revision:
Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 13 - Disposal Considerations.

Prepared by: Toxicology and Hazard Communication
   Pfizer Global Environment, Health, and Safety
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End of Safety Data Sheet