



MATERIAL SAFETY DATA SHEET

Revision date: 29-Jan-2007

Version: 1.1

Page 1 of 6

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

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ChemSafe (24 hours): +44 (0)208 762 8322

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

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Calcitonin Salmon	47931-85-1	256-342-8	50 or 100 IU/mL

Ingredient	CAS Number	EU EINECS List	%
Sodium chloride	7647-14-5	231-598-3	*
Acetic acid	64-19-7	200-580-7	*
Sodium acetate	127-09-3	204-823-8	*

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, parasthesia (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.

MATERIAL SAFETY DATA SHEET

Material Name: Calcitonin Salmon Solution for Injection
Revision date: 29-Jan-2007

Page 2 of 6
Version: 1.1

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

OSHA - Final PELS - TWAs:	= 10 ppm TWA = 25 mg/m ³ TWA
ACGIH Threshold Limit Value (TWA)	= 10 ppm TWA
ACGIH Threshold Limit Value (STEL)	= 15 ppm STEL
Australia STEL	= 15 ppm STEL = 37 mg/m ³ STEL
Australia TWA	= 10 ppm TWA = 25 mg/m ³ TWA

MATERIAL SAFETY DATA SHEET

Material Name: Calcitonin Salmon Solution for Injection
Revision date: 29-Jan-2007

Page 3 of 6
Version: 1.1

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:

Physical State:	Liquid solution	Color:	Colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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 LD 50 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

MATERIAL SAFETY DATA SHEET

Material Name: Calcitonin Salmon Solution for Injection
Revision date: 29-Jan-2007

Page 4 of 6
Version: 1.1

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

Calcitonin Salmon

Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	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
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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.

MATERIAL SAFETY DATA SHEET

Material Name: Calcitonin Salmon Solution for Injection
Revision date: 29-Jan-2007

Page 5 of 6
Version: 1.1

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:

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MATERIAL SAFETY DATA SHEET

Material Name: Calcitonin Salmon Solution for Injection
Revision date: 29-Jan-2007

Page 6 of 6
Version: 1.1

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End of Safety Data Sheet