

MONSANTO Company

Material Safety Data

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: POSILAC®
(Sterile Sometribove Zinc Suspension)

MSDS Number: M00015072 Date: 5/7/96

Chemical Family: Not applicable.
Generic Name: Recombinant DNA-Derived Methionyl Bovine Sometotropin
Synonyms: BST, MBS, zinc methionyl bovine somatotripin

MONSANTO COMPANY, 800 N. LINDBERGH BLVD., ST. LOUIS, MO 63167

FOR CHEMICAL EMERGENCY, SPILL LEAK, FIRE, EXPOSURE, OR ACCIDENT
Call CHEMTREC - Day or Night - 1-800-424-9300 Toll free in the continental U.S., Hawaii, Puerto Rico, Canada, Alaska, or Virgin Islands. For calls originating elsewhere: 703-527-3887 (collect calls accepted)

For additional non-emergency information, call: 1-800-833-6455

2. COMPOSITION/INFORMATION ON INGREDIENTS

<u>Component</u>	<u>CAS No.</u>
Sometribove *	102744-97-8

* Hazardous chemical(s) under the criteria of the OSHA Hazard Communication Standard (29 CFR 1910.1200).

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Appearance and Odor: White to off-white suspension, no odor.

CAUTION!
MAY CAUSE ALLERGIC SKIN REACTION.

POTENTIAL HEALTH EFFECTS

Likely Routes of Exposure: Skin contact.

Effects of Exposure

Skin contact is expected to be the primary route of occupational exposure to this product. The sometribove zinc in this product is a biosynthetic form of bovine somatotropin (a naturally occurring protein hormone produced in the pituitary gland of cows) formulated in food grade oil. Clinical studies have shown that injection of naturally occurring bovine somatotropin does not stimulate growth in humans. If swallowed, sometribove zinc is not orally active as it is digested in the gastrointestinal tract like other dietary proteins.

Skin and eye contact with this product should be avoided. It is well established that frequent skin contact with foreign proteins like sometribove zinc may cause dermatitis in susceptible individuals who become sensitized to the protein.

Allergic reactions have also occurred following inhalation of sometribove zinc as a dust; such exposures are not expected with this oil-based suspension, however.

Refer to Section 11 for toxicological information.

4. FIRST AID MEASURES

IF IN EYES: Immediately flush with plenty of water.

IF ON SKIN: Immediately flush with plenty of water while removing contaminated clothing. As soon as soap is available, wash thoroughly with soap and water. Wash clothing before reuse. Sensitized persons should avoid further contact and reuse of contaminated clothing. Get medical attention.

IF SWALLOWED: Immediate first aid is not likely to be required. A physician or Poison Control Center can be contacted for advice.

5. FIRE FIGHTING MEASURES

Flash Point: >212 degrees F (100 degrees C)

Hazardous Products of Combustion: Carbon monoxide

Extinguishing Media:

In case of fire, use water spray (fog), foam, dry chemical, or CO2.

Unusual Fire and Explosion Hazards: None

Fire Fighting Equipment: Fire fighters and others exposed to products of combustion should wear self-contained breathing apparatus. Equipment should be thoroughly decontaminated after use.

6. ACCIDENTAL RELEASE MEASURES

Contain large spills with dikes and transfer the material to appropriate containers for disposal. Absorb remaining material or small spills with an inert material and then place in a chemical waste container. Flush residual spill area with water.

Refer to Section 13 for disposal information.

7. HANDLING AND STORAGE

Avoid prolonged or repeated contact with skin.

Wash thoroughly after handling.

Storage: Store under refrigeration (2 to 8 degrees C; 36 to 46 degrees F). Do not freeze.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Eye Protection: This product does not cause significant eye irritation or eye toxicity requiring special protection. Use good industrial hygiene practice for eye protection.

Skin Protection: Although POSILAC® does not present a significant skin concern, minimize skin contamination by following good industrial hygiene practice. Wearing protective gloves is recommended. Wash hands and contaminated skin thoroughly after handling.

Attention! Repeated or prolonged contact may cause allergic skin reaction in some people.

9. PHYSICAL AND CHEMICAL PROPERTIES

Chemical Formula: $C_{978}H_{1537}N_{265}O_{286}S_9 \cdot ZN (1 \text{ to } 3)$

Appearance: White to off-white suspension.

Viscosity: $\leq 6,000$ cps

Water Solubility: <0.5 mg/ml @ 23°C

10. STABILITY AND REACTIVITY

Stability: Product is stable for 48 months when stored at 2 degrees C to 8 degrees C (36 degrees F to 46 degrees F).

Materials to Avoid: None

Hazardous Decomposition Products: None

Hazardous Polymerization: Does not occur.

11. TOXICOLOGICAL INFORMATION

Data from laboratory studies conducted by Monsanto and from the scientific literature on POSILAC® are summarized below. Single-exposure (acute) studies indicate:

Oral - Practically Nontoxic (Rat LD₅₀ - $>5,000$ mg/kg)

Dermal - No More Than Slightly Toxic (Rabbit LD₅₀ - $>2,000$ mg/kg)

Eye Irritation - Slightly Irritating (Rabbit)

Skin Irritation - Slightly Irritating (Rabbit)

Components

Data from laboratory studies conducted by Monsanto and from the scientific literature on the sometribove zinc component of POSILAC® (sterile sometribove zinc suspension):

Sometribove Zinc

Repeated skin contact with sometribove zinc dust has been reported to cause dermatitis in workers while allergic respiratory responses have been reported with exposure to high airborne concentrations of the dust. Symptoms of skin reaction include hives (urticaria) and contact dermatitis; symptoms of respiratory reaction may include an asthmatic response and hay-fever or flu-like symptoms. In human clinical trials, injection of large doses of animal (bovine) somatotropin for several weeks or months did not stimulate growth. Humans were reported to respond only to human or monkey somatotropin.

Sometribove zinc was practically nontoxic orally (rats) and no more than slightly toxic after skin application (rabbits). It was slightly irritating to rabbit skin and eyes. No growth response or adverse effects were observed with repeated (90-day) oral dosing of sometribove zinc to rats. Slight anemia with increased body and organ weights were observed following repeated (90-day) injection of rats. Sometribove zinc produced no genetic changes in standard tests using

animal cells.

Additional Information

Intentional misuse by intramuscular injection of POSILAC® in humans has resulted in large, sterile abscesses requiring surgical debridement.

12. ECOLOGICAL INFORMATION

Monsanto has not conducted environmental toxicity studies with this product.

13. DISPOSAL CONSIDERATIONS

This material when discarded is not a hazardous waste as that term is defined by the Resource, Conservation and Recovery Act (RCRA), 40 CFR 261. Dispose of packaging waste by incineration or in a landfill which complies with Federal, state, and local regulations. Used syringes and needles should be placed in a leak-resistant, puncture-resistant container for disposal in accordance with applicable Federal, state and local regulations. Consult your attorney or appropriate regulatory officials for information on such disposal.

14. TRANSPORT INFORMATION

The data provided in this section is for information only. Please apply the appropriate regulations to properly classify your shipment for transportation.

This product is not hazardous under the applicable DOT, ICAO/IATA, or IMDG regulations.

15. REGULATORY INFORMATION

TSCA Inventory: All components are listed or exempted.

SARA Hazard Notification

Hazard Categories Under Title III Rules (40 CFR 370): Not applicable

Section 302 Extremely Hazardous Substances: Not applicable

Section 313 Toxic Chemical(s): Not applicable

CERCLA Reportable Quantity: Not applicable

Refer to Section 2 for OSHA Hazardous Chemical(s).

16. OTHER INFORMATION

Reason for revision: Routine review and conversion to the 16 section format. Supersedes MSDS dated June 1993.

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