# MATERIAL SAFETY DATA SHEET

Date: April 11, 2008



## I. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: **Leukine®** (lyophyilized powder)
Active Ingredient Name: Sargramostim
Product Description: Recombinant human granulocyte macrophage colony stimulating factor

Manufactured by: Bayer Health Care Pharmaceuticals LLC
Seattle, WA 98101

Product Information and
Emergency Telephone Number:

1-888-84BAYER

## II. COMPOSITION / INFORMATION ON INGREDIENTS

| Ingredient | CAS No. | Exposure Limits | (mg/L) |
|---|---|---|---|
| Sargramostim | N/A | N/E | 250µg |
| Mannitol, USP | 9001-65-4 | N/E | 40mg |
| Sucrose, NF | 57-50-1 | N/E | 10mg |
| Tromethamine,USP | 77-86-1 | N/E | 1.2mg |

## III. HAZARDS IDENTIFICATION

Potential Health Effects

**CAUTION: Do not administer to neonates if reconstituted with solutions containing benzyl alcohol (i.e. Bacteriostatic Water for Injection, USP).**

## IV. FIRST AID MEASURES

EYES: Flush with copious amounts of water for at least 15 minutes. Ensure flushing by separating the eyelid(s) with fingers. See a physician if irritation develops

SKIN: Wash with soap and water.

INGESTION: If swallowed seek medical attention.

INHALATION: Not an expected route of entry.

N/E – Not Established

# MATERIAL SAFETY DATA SHEET



## V. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES: Not flammable, not combustible

FLAMMABLE LIMITS: N/A

AUTOIGNITION TEMPERATURE: N/A

HAZARDOUS COMBUSTION PRODUCTS: None known

EXTINGUISHING MEDIA: Water, $CO_2$, foam, or dry chemical as appropriate to the source of the fire.

FIREFIGHTING INSTRUCTIONS: Use appropriated extinguishing media for surrounding fire. Use appropriate personal protective equipment and self-contained breathing apparatus.

## VI. ACCIDENTAL RELEASE MEASURES

SMALL SPILL: Wear personal protective equipment. Wipe spill with appropriate material and place in a suitable container for proper disposal. Wash area with soapy water after product has been picked up.

## VII. HANDLING AND STORAGE

STORAGE: Refrigerate at 36-46°F (2-8°C). **Do Not Freeze.** Depending on the diluent will determine the expiration of the reconstituted lyophilized powder.

## VIII. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: Under normal use, none required.

RESPIRATORY PROTECTION: Under normal use, none required.

SKIN PROTECTION: Use universal precautions during administration.

EYE PROTECTION: Under normal use, none required.

## IX. PHYSICAL AND CHEMICAL PROPERTIES

BOILING POINT: N/A
MELTING POINT: N/A
VAPOR PRESSURE: N/A
VAPOR DENSITY: N/A
SOLUBILITY IN WATER: extremely soluble
DENSITY (37°C):
pH: 7.4± 0.3
ODOR: None
APPEARANCE: sterile, white, preservative-free lyophilized compressed powder/cake

## X. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable

INCOMPATIBILITY: None known

HAZARDOUS DECOMPOSITION PRODUCTS: None known

HAZARDOUS POLYMERIZATION: None known

## XI. TOXICOLOGICAL INFORMATION

EYE: Animal studies have not been conducted with LEUKINE® to evaluate ocular irritation.

SKIN: Animal studies have not been conducted with LEUKINE® to evaluate dermal irritation. Precautions should be taken to minimize contact with the skin.

INGESTION: Animal studies have not been conducted with LEUKINE® to evaluate toxcity after ingestion.

INHALATION: N/A

CHRONIC/CARCINOGENICITY: Animal studies have not been conducted with LEUKINE® to evaluate carcinogenic potential. No visceral organ toxicity was observed following daily subcutaneous administration of leukine to primates for 30 days.

TERATOLOGY: Animal reproduction studies have not been conducted with LEUKINE®. It is not known if LEUKINE® can cause fetal harm when administered to a pregnant woman or can affect reproductive capability.

REPRODUCTION: Animal reproduction studies have not been conducted with LEUKINE®. It is not known if LEUKINE® can cause fetal harm when administered to a pregnant woman or can affect reproductive capability.

MUTAGENICITY: No studies have been conducted with LEUKINE® to evaluate mutagenic potential.

# MATERIAL SAFETY DATA SHEET



## XII. ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION: N/A

CHEMICAL FATE INFORMATION: Not expected to enter terrestrial or air compartments. Expected to enter aquatic compartment.

## XIII. DISPOSAL CONSIDERATIONS:

Observe all Federal, State, and local environmental regulations.

## XIV. TRANSPORT INFORMATION

Not regulated by the Department of Transportation (DOT). Shipped on ice packs 36º-46ºF (2-8ºC).

## XV. REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

OSHA: None

CERCLA: SARA Hazard Category: Not regulated

SECTION 313: Not listed

STATE REGULATIONS:

VOLATILE ORGANIC COMPOUNDS (VOC): None

## XVI. OTHER INFORMATION

MSDS STATUS:

THE INFORMATION RELATES TO THIS SPECIFIC MATERIAL. IT MAY NOT BE VALID FOR THIS MATERIAL IF USED IN COMBINATION WITH ANY OTHER MATERIALS OR IN ANY PROCESS. IT IS THE USER'S RESPONSIBILITY TO SATISFY ONESELF AS TO THE SUITABILITY AND COMPLETENESS OF THIS INFORMATION FOR HIS OWN PARTICULAR USE.

THE INFORMATION PROVIDED ABOVE IS BELIEVED TO BE CORRECT. HOWEVER, BAYER HEALTHCARE PHARMACEUTICALS, INC. MAKES NO REPRESENTATION AS TO THE ACCURACY OR COMPLETENESS OF THIS INFORMATION. IT IS EXPECTED THAT THE USER WILL DETERMINE THE SUITABILITY OF THE INFORMATION FOR THE INTENDED APPLICATIONS AND USE APPROPRIATE SAFETY PROCEDURES AND PRECAUTIONS