

MATERIAL SAFETY DATA SHEET (MSDS)

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

Identification of the product

Catalogue No.:	N/A
Product Name:	Rebif® 8.8 µg, 22 µg (6 MIU), 44 µg (12 MIU) Interferon beta-1a (INN)
Pharmaceutical Form:	Liquid preparation for injection
<i>Manufacturer/supplier information</i>	
Company:	EMD Serono, Inc. One Technology Place, MA-02370 Rockland, USA
Emergency telephone no.:	+1.800.283.8088 x5562 or Product Information – Chemtrec: +1.800.424.9300

2. COMPOSITION/INFORMATION ON INGREDIENT AND EXCIPIENTS

Interferon beta-1a (INN):	CAS N°:	9008-11-1
	% present:	Less than 1%
	Molar mass:	Glycoprotein with a relative mass of approximately 22'500 Daltons
	Molecular formula:	N/A
	EC-N°:	232-710-3
Mannitol:	CAS N°:	69-65-8
	% present:	5.5%
	Molar mass:	182.17
	Molecular formula:	C ₆ H ₁₄ O ₆
	EC-N°:	200-711-8
Human Serum Albumin:	CAS N°:	260-855-2
	% present:	Less than 1%
	Molar mass:	N/A
	Molecular formula:	N/A
	EC-N°:	57622-87-4
Sodium Acetate Trihydrate:	CAS N°:	6131-90-4
	% present:	Less than 1%
	Molar mass:	136.08
	Molecular formula:	CH ₃ COONa, 3H ₂ O
	EC-N°:	57622-87-4

3. HAZARDS IDENTIFICATION

The Drug Product is a proteinaceous liquid and does not have specific Fire or Explosion Hazards other than those associated with glass syringes.

No data are available neither on oral or dermal absorption nor on dermal or eye irritation.

NOTE: Liquid Rebif® in syringes is supplied with a needle attached to each syringe. Care should be taken to avoid "needle stick" injuries.

Effects on overexposure

Inhalation: If material becomes airborne there is a potential for inhalation. The extent of systemic absorption of the material after inhalation is not known. Based on the harmful effects on pregnancy noted in monkeys (see section 11) there is a warning resulting from the occupational exposure if suitable PPD (Personal Protection Devices) are not worn.

Skin contact: Exposure may occur via skin contact if PPD (Personal Protection Devices) are not worn.

Ingestion: Ingestion of large quantities of this material in an occupational setting would not be expected to occur. Ingestion of trace amount might occur when material contacts hands and hands are not washed prior to eating, drinking or smoking.

Emergency overview: Change in appearance: hygroscopic, changes color on exposure to light.

4. FIRST AID MEASURES

In case of inhalation:	Move the subject into fresh air if possible. Seek medical attention or advice if discomfort persists or symptoms appear. If subject's breathing is difficult, give oxygen and call a physician. If subject stops breathing, give artificial respiration and call a physician.
In case of skin contact:	Remove contaminated clothes, glass and other debris as necessary. Wash affected area of skin with soap and clean water. Seek medical attention or advice if skin becomes sensitive, tender, or symptoms appear.
In case of eye contact:	Call a physician. Immediately flush eyes with plenty of clean water for at least 15 minutes.
In case of ingestion, great amounts:	Provided the subject is conscious wash mouth out with fresh drinking water. If swallowed, drink copious amounts of fresh drinking water. Seek medical attention or advice if discomfort appears, persists or symptoms appear.

5. FIRE-FIGHTING MEASURES

Flammability:	Not known
Appropriate means of extinguishing:	Use Water Spray, Carbon Dioxide (CO ₂), ABC Dry Powder or foam as appropriate for the surroundings materials, severity of the fire, and prevailing regulations.
Means of extinguishing NOT to be used:	Not known
Hazardous combustion products:	Development of CO ₂ and NO ₂ . Syringe plungers are halo-butyl compounds, which will produce dense, toxic black smoke in a fire.
Special protective devices for fire fighters:	As necessary, wear self-contained breathing apparatus (SCBA), and full body protective clothing as appropriate for the surrounding materials, severity of the fire and prevailing regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Wear gloves, safety goggles and impervious clothing. Avoid material coming into contact with eyes, skin, clothing and inhalation. Be careful of glass fragments if syringes are broken. If deemed necessary for added protection, especially for large spills wear a face mask. In the USA an NIOSH approved Dusk/Mist respirator would be suitable.
Environment precautions:	Keep out of drains, prevent entry to surface water, groundwater and soil.
Recovery of the spilled material:	Collect material in appropriate container for disposal. Avoid the excessive generation of dust, aerosols and mist. Ventilate area and wash spilled site after material pick up is complete.

7. HANDLING AND STORAGE

Room ventilation and storage:	If necessary, use adequate dust/vapor control, refer to product labeling.
Special precautions: (See also Section 8)	Handle with approved clothing. Refer to recommendation reported in the product labeling.
Recommended temperature:	Refer to product labeling
Humidity, light and other factors:	Refer to product labeling
Containers:	Keep unopened in the original container
Other storage precautions:	Human Serum Albumin is regulated by the FDA under 21 CFR 640.80 to 640.86 & in Europe by the National Health Authorities, EC and European Pharmacopoeia (Mono. 255).

8. EXPOSURE CONTROLS/PERSONAL AND SPECIAL PROTECTION

Ventilation/containment:	Local exhaust at point of manufacture or use. No occupational exposure limits established	
Clothing/equipment:	Requested:	Details:
Respiratory protection	NO	—
Hand protection	YES	Protective gloves
Eye protection	YES	Safety glasses with side shields
Skin protection	YES	Protective covering for exposed areas of skin
Industrial hygiene	YES	General ventilation (process dependent)

9. PHYSICAL AND CHEMICAL PROPERTIES:

Appearance	Liquid.
<i>Properties of the substance</i>	
Color, odor:	Colorless, odorless
pH value:	3.4 to 5.0
Melting point	No data available.
Boiling temperature	No data available.
Vapor pressure	No data available.
Solubility	No data available.
Solubility in water	Soluble
Partition coefficient	No data available.
Flammability	No data available.
Miscellaneous Information	Refer to product labeling and insert. Where product is for use in a clinical trial as an investigational drug, please refer to the Investigator Brochure for further information on toxicology and safety.

10. STABILITY AND REACTIVITY

Conditions to be avoided:	Refer to labeling
Substances to be avoided:	Refer to labeling
Hazardous decomposition products:	No decomposition products other than the one arising from thermal combustion products include CO ₂ and NO ₂ . Stoppers are halogen butyl compounds producing dense, toxic black smoke in a fire.
Other precautions:	Handle to prevent damage to the containers during shipping.

11. HEALTH HAZARD DATA/TOXICOLOGICAL INFORMATION

Oral toxicity:	No data available.
Dermal toxicity:	No data available.
Toxicity by inhalation:	No data available.
Eye irritation:	No data available.
Skin irritation:	No data available.
Skin sensitization:	No data available.
Mutagenicity:	Negative for "in vitro" and "in vivo" gene mutation and chromosomal aberration tests.
Carcinogen status:	None
NTP	No NTP status
IARC	No IARC status
Carcinogenesis:	Not performed; not expected.
<i>Other available toxicity data:</i>	
Teratogenesis:	No teratogenic effect up to 1.8 MIU per kg in monkeys when administered intramuscularly. Possible increased risk of abortion.
Chronic effects:	No toxic effects up to 1 MIU per kg in rats or monkeys when administered by intravenous or intramuscular route or up to approx. 10 MIU per kg in monkeys by subcutaneous route.
LD ₅₀ :	LD ₅₀ greater than 20 MIU per kg in monkeys, mice, rats when administered by intravenous or intramuscular route.

12. ECOLOGICAL INFORMATION

In the USA this product is not regulated by the EPA as a hazardous substance.

Environmental persistence:	No data available.
Toxicity to aquatic life:	No data available.
Other information on ecotoxicity:	No data available.

13. DISPOSAL CONSIDERATIONS

Observe country, state and local environment regulations defining disposal of pharmaceutical waste. Where product is used in clinical trials as an investigational drug, the disposal of product past its expiration date may be subject to additional requirements, depending on the country and local regulations. In the USA contact Serono Inc. Customer Service at +1.800.398.4567 for disposal instructions.

14. TRANSPORT INFORMATION

Drug transportation may be subject to local country regulations.

15. REGULATORY INFORMATION

Classification	N/A (see Section 3)
Labeling symbol(s):	N/A
Labeling risk-phrases:	N/A
Labeling safety-phrases:	N/A

16. OTHER INFORMATION*Additional information about the product.*

Additional information is available in the product insert for Rebif®. Where product is for use in a clinical trial as an investigational drug, please refer to the Investigator Brochure for further information on toxicology and safety. In the case of pre-filled syringes, a needle is attached to each syringe, therefore care should be taken to avoid "needle stick" injuries.

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.

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