

Safety Data Sheet

As required by 29 CFR 1910.1200, (EC) N. ° 1907/2006, (EC) N. ° 1272/2008

Version: 3
Effective Date: 26.AUG.2013
Revision Date: 18.APR.2016

Section 1: Product and Company Identification

Product Name : AVONEX[®]
Chemical Name : Interferon beta-1a
Intended Use : Biotherapeutic
Company : Biogen
225 Binney Street
Cambridge MA, 02142
(617) 679-2000
Emergency Phone : CHEMTREC (800) 424-9300

Section 2: Hazards Identification

Hazard Class / Category : Not Classified

Other Hazard Information

Note: Avonex[®] is a recombinant form of the naturally produced protein interferon beta 1a. The final product is sold as a prescription, injectable drug in liquid form in a pre-filled syringe (0.5 ml). AVONEX[®] Liquid is not considered hazardous per the criteria under the OSHA Hazard Communication Standard (29 CFR 1910.1200) or (EC) No. 1907/2006 and (EC) No. 1272/2008. Although the health effects of occupational exposure to this product are not fully known or characterized, no adverse effects are anticipated as a result of occupational or incidental exposure.

Section 3: Composition / Information on Ingredients

Chemical Name	Quantity	CAS No.	EC No.
Interferon beta-1a	30 mcg	194739-10-1	Not available
Sodium acetate trihydrate	0.79 mg	6131-90-4	204-823-8
Arginine hydrochloride	15.8 mg	627-75-8	211-010-1
Glacial acetic acid	0.25 mg	64-19-7	200-580-7
Polysorbate 20	0.025 mg	9005-64-5	Not available
Sterile water for Injection	balance	7732-18-5	231-791-2

Common Name / Synonyms : recombinant human interferon beta, r-HuIFN- β

Section 4: First Aid Measures

Eyes

Flush with water for 15 minutes. Seek medical attention if irritation occurs/persists.

Skin

Remove contaminated clothing. Wash exposed area with water for 15 minutes. Seek medical attention if irritation occurs/persists.

Inhalation

Safety Data Sheet

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Move person to the fresh air. If not breathing give artificial respiration, treat symptomatically and supportively, get medical attention.

Ingestion

Rinse mouth with water and seek medical attention, if required.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media

Use water spray, carbon dioxide, ABC dry chemical or foam.

Unsuitable Extinguishing Media / Unusual Risks

None Known

Special Fire-Fighting Equipment for Fire-Fighters

No data available

Section 6: Accidental Release Measures

Personal Precautions and Protection

Wear impervious gloves, lab coat and safety glasses.

Environmental Precautions

Do not allow product to spill into public drains / sewers.

Clean Up Procedures

Place clean up debris in appropriate containers and dispose of in accordance with local, state and federal laws regarding waste management.

Section 7: Storage and Handling

Handling

Avoid direct contact.

Storage

Store syringes at 2-8 °C (36-46 °F) in the original packaging to protect from light. Do not freeze. Luer lock, but not luer slip, syringes can be stored for 1 week at room temperature (15-30 °C) prior to use.

Specific Uses

Prescription biotherapeutic drug; use as directed by a licensed health care provider.

Section 8: Exposure Controls / Personal Protection

Exposure Routes

Inhalation, skin and eye contact; accidental ingestion or needlestick.

Occupational Exposure Limits: None

Other PPE

Wear impervious gloves, lab coat, and safety glasses to prevent skin and eye contact.

Section 9: Physical and Chemical Properties

Molecular weight : Not applicable for mixture

Safety Data Sheet

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pH	: 4.8
Boiling point	: No data available
Melting point	: No data available
Vapor Pressure	: No data available
Solubility (water)	: Completely soluble
Solubility (other solvents)	: No data available
Evaporation rate	: No data available
Vapor density	: No data available
Specific gravity	: No data available
% volatile	: No data available
Partition coefficient	: No data available

Physical form: Liquid
Odor: None
Appearance/Color: clear

Section 10: Stability and Reactivity

Stability: Stable

Incompatible materials / conditions

No data available

Hazardous decomposition products

None known

Hazardous polymerization

Will not occur

Section 11: Toxicological Information

The chemical, physical and toxicological properties of this product have not been fully characterized. Avoid direct contact.

Acute Toxicity

The most common adverse events in patients following administration of interferon beta-1a by intravenous, subcutaneous or intramuscular injection are flu-like symptoms, muscle ache, fever, chills and asthenia. Doses of up to 90 mcg (18MU) have been administered subcutaneously to human patients in clinical trials.

No mortality or significant toxicity was observed after single doses of 200 mcg/kg (40MU/kg) IV in rats; 330 mcg/kg IV and 990 mcg/kg (18MU/kg)SC in mice; 90 mcg/kg SC in guinea pigs; 15 mcg IM in rabbits or 50 mcg/kg SC in monkeys..

Signs and Symptoms of Exposure

No mortality or signs of toxicity

Effects by inhalation, dermal contact, ingestion or eye contact

Minimal intramuscular irritation was observed in rabbits receiving a single IM injection of Avonex[®]. This degree of irritation is typical of the trauma expected with any IM injection.

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Sensitization

Interferon beta-1a produced no sensitizing properties in the skin of guinea pigs.

Chronic Toxicity

Recombinant human interferon beta-1a was well tolerated in rhesus monkeys following daily repeat (2 to 9 weeks) subcutaneous administration up to 50 mcg/kg (10MU/kg), excluding expected fever and antibody production to both human serum albumin and recombinant human interferon beta. Slight, but reversible decreases in platelets were observed in monkeys at the 50 mcg/kg dose level

Carcinogenicity

No data available. After approximately 2 weeks of treatment, the monkeys developed a neutralizing antibody response to interferon beta-1a; for this reason, chronic repeat dose toxicity testing with interferon beta-1a alone was not performed. Interferon beta-1a is not listed as a carcinogen by OSHA, NTP or IARC

Genotoxicity

Interferon beta 1a was negative in the Ames microbial mutagenicity test and in an in-vivo cytogenetic assay in human lymphocytes in presence and absence of metabolic activation.

Reproductive and Developmental Toxicity:

No male fertility studies have been performed in male rhesus monkeys, but there is no published information to suggest that interferons would have an effect on testicular function. In a female fertility study of interferon beta-1a in rhesus monkeys 4 of the 6 monkeys dosed SC at 33 mcg/kg daily for 5 consecutive cycles failed to ovulate during the treatment cycle. Ovarian function returned during the subsequent 2 post-treatment cycles suggesting that anovulation related to the test article was reversible. The NOEL was 0.8 mcg/kg.

The reproductive toxicity of interferon beta 1a has not been studied in humans. In pregnant monkeys given interferon beta 1a at 100 times the recommended weekly human dose, no teratogenic or other adverse effects on fetal development were observed. Abortifacient activity was evident following 3 to 5 doses at this level. No abortifacient effects were observed in monkeys treated at 2 times the recommended weekly human dose. Treatment of monkeys with interferon beta 1a at 2 times the recommended weekly human dose had no effects on cycle duration or ovulation.

Target Organs: No target organ toxicity

Section 12: Ecological Information

Ecotoxicity: No Data Available

Mobility: No Data Available

Environmental persistence: No Data Available

Bioaccumulation: No Data Available

Section 13: Disposal Considerations

Product Disposal

Avonex[®] is not a RCRA hazardous waste as defined by US EPA.

Packaging Disposal

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Dispose of in accordance with applicable federal, state and local regulations.

Other regulatory information

None

Section 14: Transport Information

ICAO / IATA

Proper Shipping Name, Class, UN Number, Packing Group
Non Hazardous

RID / ADR / DOT

Proper Shipping Name, Class, UN Number, Packing Group
Non Hazardous

IMDG

Proper Shipping Name, Class, UN Number, Packing Group
Non Hazardous

Section 15: Regulatory Information

Australia Regulatory Status : ARTG entry
95419 AVONEX interferon beta-1a (rch)
30 microgram/0.5mL injection pre-filled syringe
is a registered Medicine

Australian Poisons Schedule : (S4) Prescription Medicine Only

The Human Serum Albumin used in the formulation of Avonex[®] meets the requirements of the USP, EP and 21 CFR Part 640.81(e)

REACH (EU regulations) : *As a medicinal product;*
Restrictions on use - Not applicable
Authorization - Not applicable

OSHA Classification : None

R Phrases : None

S Phrases : None

Section 16: Other Information

DISCLAIMER: The above mentioned data are based on Biogen's best present knowledge of this product. Biogen cannot guarantee completeness or accuracy of the information contained herein, and disclaims all liability for incompleteness or inaccuracy of the information and for any claims of damages arising from handling or use of this product.

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