

## 1. Identification

**Product identifier** Interferon Beta-1A

**Other means of identification**

**Catalog number** 1342401

**Recommended use** Specified quality tests and assay use only.

**Recommended restrictions** Not for use as a drug. Not for administration to humans or animals.

**Manufacturer/Importer/Supplier/Distributor information**

**Manufacturer**

**Company name** U. S. Pharmacopeia

**Address** 12601 Twinbrook Parkway  
Rockville  
MD  
20852-1790  
United States

**Telephone** RS Technical Services 301-816-8129

**Website** www.usp.org

**E-mail** RSTECH@usp.org

**Emergency phone number** CHEMTREC within US & 1-800-424-9300  
Canada  
CHEMTREC outside US & +1 703-527-3887  
Canada

## 2. Hazard(s) identification

**Physical hazards** Not classified.

**Health hazards** Reproductive toxicity Category 2

**Environmental hazards** Not classified.

**OSHA defined hazards** Not classified.

**Label elements**



**Signal word** Warning

**Hazard statement** Suspected of damaging fertility or the unborn child.

**Precautionary statement**

**Prevention** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.

**Response** If exposed or concerned: Get medical advice/attention.

**Storage** Store locked up.

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.

**Hazard(s) not otherwise classified (HNOC)** None known.

**Supplemental information** Highly potent pharmacologically active material.

## 3. Composition/information on ingredients

### Mixture

| Chemical name            | Common name and synonyms | CAS number | %     |
|--------------------------|--------------------------|------------|-------|
| Water                    |                          | 7732-18-5  | 96.56 |
| L-Arginine Hydrochloride |                          | 15595-35-4 | 3.1   |

| Chemical name             | Common name and synonyms                | CAS number  | %     |
|---------------------------|-----------------------------------------|-------------|-------|
| Sodium Acetate Trihydrate |                                         | 6131-90-4   | 0.16  |
| Interferon Beta-1A        |                                         | 194739-10-1 | 0.13  |
| Glacial Acetic Acid       | Methanecarboxylic acid<br>Ethanoic acid | 64-19-7     | 0.047 |

#### 4. First-aid measures

|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Inhalation</b>                                                             | Move to fresh air. Call a physician if symptoms develop or persist.                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Skin contact</b>                                                           | Rinse skin with water/shower. Get medical attention if irritation develops and persists.                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Eye contact</b>                                                            | Rinse with water. Get medical attention if irritation develops and persists.                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Ingestion</b>                                                              | Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Most important symptoms/effects, acute and delayed</b>                     | Highly potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Indication of immediate medical attention and special treatment needed</b> | Provide general supportive measures and treat symptomatically.                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>General information</b>                                                    | Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. |

#### 5. Fire-fighting measures

|                                                                      |                                                                                                                                                                                                         |
|----------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Suitable extinguishing media</b>                                  | Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).                                                                                                                                             |
| <b>Unsuitable extinguishing media</b>                                | Do not use water jet as an extinguisher, as this will spread the fire.                                                                                                                                  |
| <b>Specific hazards arising from the chemical</b>                    | No unusual fire or explosion hazards noted.                                                                                                                                                             |
| <b>Special protective equipment and precautions for firefighters</b> | Wear suitable protective equipment.                                                                                                                                                                     |
| <b>Fire fighting equipment/instructions</b>                          | Move containers from fire area if you can do so without risk. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. |
| <b>Specific methods</b>                                              | Use standard firefighting procedures and consider the hazards of other involved materials.                                                                                                              |
| <b>General fire hazards</b>                                          | No unusual fire or explosion hazards noted.                                                                                                                                                             |

#### 6. Accidental release measures

|                                                                            |                                                                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Personal precautions, protective equipment and emergency procedures</b> | Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of vapors. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS. |
| <b>Methods and materials for containment and cleaning up</b>               | Absorb spillage with suitable absorbent material. For waste disposal, see section 13 of the SDS.                                                                                                                                                                                                 |
| <b>Environmental precautions</b>                                           | Clean surface thoroughly to remove residual contamination.<br>Avoid discharge into drains, water courses or onto the ground.                                                                                                                                                                     |

#### 7. Handling and storage

|                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|---------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Precautions for safe handling</b>                                | As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. |
| <b>Conditions for safe storage, including any incompatibilities</b> | Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.                                                                                                                                                                                                                                                                                                       |

#### 8. Exposure controls/personal protection

##### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

**US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**

| Components                        | Type | Value    |
|-----------------------------------|------|----------|
| Glacial Acetic Acid (CAS 64-19-7) | PEL  | 25 mg/m3 |
|                                   |      | 10 ppm   |

**US. ACGIH Threshold Limit Values**

| Components                        | Type | Value  |
|-----------------------------------|------|--------|
| Glacial Acetic Acid (CAS 64-19-7) | STEL | 15 ppm |
|                                   | TWA  | 10 ppm |

**US. NIOSH: Pocket Guide to Chemical Hazards**

| Components                        | Type | Value    |
|-----------------------------------|------|----------|
| Glacial Acetic Acid (CAS 64-19-7) | REL  | 25 mg/m3 |
|                                   |      | 10 ppm   |
|                                   | STEL | 37 mg/m3 |
|                                   |      | 15 ppm   |

**Biological limit values**

No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls**

No open handling. Use closed and sealed systems for tasks with the potential for aerosol generation (vortexing, pipetting, pumping). Control the potential for spills and leaks by securing all connections. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

**Individual protection measures, such as personal protective equipment****Eye/face protection**

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

**Skin protection****Hand protection**

Wear double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

**Other**

Train employees in proper gowning and degowning practices. Wear disposable laboratory coat and disposable sleeve covers appropriate to the task, two pairs of gloves, and safety glasses with side shields. An anteroom or transition area is recommended for gowning and degowning. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

**Respiratory protection**

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**

Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

**9. Physical and chemical properties****Appearance**

Appearance descriptions are general information and not specific to any USP lot.

**Physical state**

Liquid.

**Form**

Liquid.

**Color**

Pale yellow.

**Odor**

Not available.

**Odor threshold**

Not available.

**pH**

4.5 - 5.1

**Melting point/freezing point**

Not available.

**Initial boiling point and boiling range**

212 °F (100 °C)

**Flash point**

Not available.

**Evaporation rate**

Not available.

Flammability (solid, gas) Not applicable.

**Upper/lower flammability or explosive limits**

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

**Solubility(ies)**

Solubility (water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

## 10. Stability and reactivity

**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability** Material is stable under normal conditions.

**Possibility of hazardous reactions** No dangerous reaction known under conditions of normal use.

**Conditions to avoid** Contact with incompatible materials.

**Incompatible materials** Strong oxidizing agents. Strong bases.

**Hazardous decomposition products** SO<sub>x</sub>, NO<sub>x</sub>, Cl<sup>-</sup>. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

**Information on likely routes of exposure**

**Inhalation** Knowledge about health hazard is incomplete.

**Skin contact** Knowledge about health hazard is incomplete.

**Eye contact** Knowledge about health hazard is incomplete.

**Ingestion** Knowledge about health hazard is incomplete.

**Symptoms related to the physical, chemical, and toxicological characteristics** Gastrointestinal disturbances. Weakness. Fever. Chills. Muscle pain. Seizures.

**Information on toxicological effects**

**Acute toxicity**

| Components                        | Species    | Test Results       |
|-----------------------------------|------------|--------------------|
| Glacial Acetic Acid (CAS 64-19-7) |            |                    |
| <b><u>Acute</u></b>               |            |                    |
| <b>Dermal</b>                     |            |                    |
| LD50                              | Rabbit     | 1060 mg/kg         |
| <b>Inhalation</b>                 |            |                    |
| LC50                              | Guinea pig | 5000 mg/l, 1 Hours |
|                                   | Mouse      | 5620 mg/l, 1 Hours |
|                                   | Rat        | 11.4 mg/l, 4 Hours |
| <b>Oral</b>                       |            |                    |
| LD50                              | Mouse      | 4960 mg/kg         |
|                                   | Rabbit     | 1200 mg/kg         |
|                                   | Rat        | 3310 mg/kg         |

|                                                                       |                                                                                                                          |                                                                                                                                                                                                                                     |
|-----------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Skin corrosion/irritation</b>                                      | Knowledge about health hazard is incomplete.                                                                             |                                                                                                                                                                                                                                     |
| <b>Serious eye damage/eye irritation</b>                              | Knowledge about health hazard is incomplete.                                                                             |                                                                                                                                                                                                                                     |
| <b>Local effects</b>                                                  |                                                                                                                          |                                                                                                                                                                                                                                     |
| Glacial Acetic Acid                                                   |                                                                                                                          | Eye irritancy test<br>Result: Severe irritation and corneal damage.<br>Species: Rabbit<br>Skin irritancy test<br>Result: Corrosion.<br>Species: Rabbit                                                                              |
| <b>Respiratory or skin sensitization</b>                              |                                                                                                                          |                                                                                                                                                                                                                                     |
| <b>Respiratory sensitization</b>                                      | Knowledge about health hazard is incomplete.                                                                             |                                                                                                                                                                                                                                     |
| <b>Skin sensitization</b>                                             | Knowledge about sensitization hazard is incomplete.                                                                      |                                                                                                                                                                                                                                     |
| Interferon Beta-1A                                                    |                                                                                                                          | Skin sensitization<br>Result: Negative.<br>Species: Guinea pig                                                                                                                                                                      |
| <b>Germ cell mutagenicity</b>                                         | Knowledge about mutagenicity is incomplete.                                                                              |                                                                                                                                                                                                                                     |
| <b>Mutagenicity</b>                                                   |                                                                                                                          |                                                                                                                                                                                                                                     |
| Interferon Beta-1A                                                    |                                                                                                                          | Ames test<br>Result: Negative.                                                                                                                                                                                                      |
| Glacial Acetic Acid                                                   |                                                                                                                          | Assays in <i>S. typhimurium</i> and <i>E. coli</i><br>Result: Negative.<br>Clastogenicity study in Chinese hamster ovary cells<br>Result: Negative.                                                                                 |
| Interferon Beta-1A                                                    |                                                                                                                          | Mutagenicity: In vitro chromosomal aberration assay in lymphocytes<br>Result: Negative.<br>Species: Human                                                                                                                           |
| Glacial Acetic Acid                                                   |                                                                                                                          | Sister chromatid exchange assay in human peripheral lymphocytes<br>Result: Negative.                                                                                                                                                |
| <b>Carcinogenicity</b>                                                | Knowledge about carcinogenicity is incomplete.                                                                           |                                                                                                                                                                                                                                     |
| <b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>         |                                                                                                                          |                                                                                                                                                                                                                                     |
| Not listed.                                                           |                                                                                                                          |                                                                                                                                                                                                                                     |
| <b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b> |                                                                                                                          |                                                                                                                                                                                                                                     |
| Not regulated.                                                        |                                                                                                                          |                                                                                                                                                                                                                                     |
| <b>US. National Toxicology Program (NTP) Report on Carcinogens</b>    |                                                                                                                          |                                                                                                                                                                                                                                     |
| Not listed.                                                           |                                                                                                                          |                                                                                                                                                                                                                                     |
| <b>Reproductive toxicity</b>                                          | Suspected of damaging fertility or the unborn child.                                                                     |                                                                                                                                                                                                                                     |
| <b>Reproductivity</b>                                                 |                                                                                                                          |                                                                                                                                                                                                                                     |
| Interferon Beta-1A                                                    |                                                                                                                          | 33 microgram/kg Reproductivity, administered to females subcutaneously.<br>Result: Failure to ovulate.<br>Species: Monkey<br>Reproductivity / Developmental<br>Result: An increase in miscarriages was observed.<br>Species: Monkey |
| L-Arginine Hydrochloride                                              |                                                                                                                          | Reproductivity / Developmental: Rabbits and mice, 12 times the human dose.<br>Result: No impaired fertility or harm to fetuses noted.                                                                                               |
| <b>Specific target organ toxicity - single exposure</b>               | Knowledge about health hazard is incomplete.                                                                             |                                                                                                                                                                                                                                     |
| <b>Specific target organ toxicity - repeated exposure</b>             | Knowledge about health hazard is incomplete.                                                                             |                                                                                                                                                                                                                                     |
| <b>Aspiration hazard</b>                                              | Knowledge about health hazard is incomplete.                                                                             |                                                                                                                                                                                                                                     |
| <b>Further information</b>                                            | Highly potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects. |                                                                                                                                                                                                                                     |

## 12. Ecological information

### Ecotoxicity

| Components                        |      | Species                        | Test Results          |
|-----------------------------------|------|--------------------------------|-----------------------|
| Glacial Acetic Acid (CAS 64-19-7) |      |                                |                       |
| <b>Aquatic</b>                    |      |                                |                       |
| <i>Acute</i>                      |      |                                |                       |
| Crustacea                         | EC50 | Water flea (Daphnia magna)     | 65 mg/l, 48 hours     |
| Fish                              | LC50 | Bluegill (Lepomis macrochirus) | 75 mg/l, 96 hours     |
|                                   |      | Oncorhynchus mykiss            | > 1000 mg/l, 96 hours |

**Persistence and degradability** No data is available on the degradability of this product.

### Bioaccumulative potential

#### Octanol/water partition coefficient log Kow

|                     |                  |
|---------------------|------------------|
| Glacial Acetic Acid | -0.17            |
|                     | -0.31, at 20 ° c |

**Mobility in soil** No data available.

**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

|                                              |                                                                                                                                                                                                                            |
|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Disposal instructions</b>                 | Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. |
| <b>Local disposal regulations</b>            | Dispose in accordance with all applicable regulations.                                                                                                                                                                     |
| <b>Hazardous waste code</b>                  | The waste code should be assigned in discussion between the user, the producer and the waste disposal company.                                                                                                             |
| <b>Waste from residues / unused products</b> | Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).                                                            |
| <b>Contaminated packaging</b>                | Since emptied containers may retain product residue, follow label warnings even after container is emptied.                                                                                                                |

## 14. Transport information

### DOT

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not established.

**General information** It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory information

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

#### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

#### CERCLA Hazardous Substance List (40 CFR 302.4)

Glacial Acetic Acid (CAS 64-19-7) Listed.

#### SARA 304 Emergency release notification

Not regulated.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories** Immediate Hazard - No  
Delayed Hazard - Yes  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**SARA 313 (TRI reporting)**  
Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace**

Glacial Acetic Acid (CAS 64-19-7)

High priority

**US state regulations** California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories**

| Country(s) or region        | Inventory name                                                         | On inventory (yes/no)* |
|-----------------------------|------------------------------------------------------------------------|------------------------|
| Australia                   | Australian Inventory of Chemical Substances (AICS)                     | No                     |
| Canada                      | Domestic Substances List (DSL)                                         | No                     |
| Canada                      | Non-Domestic Substances List (NDSL)                                    | No                     |
| China                       | Inventory of Existing Chemical Substances in China (IECSC)             | No                     |
| Europe                      | European Inventory of Existing Commercial Chemical Substances (EINECS) | No                     |
| Europe                      | European List of Notified Chemical Substances (ELINCS)                 | No                     |
| Japan                       | Inventory of Existing and New Chemical Substances (ENCS)               | No                     |
| Korea                       | Existing Chemicals List (ECL)                                          | No                     |
| New Zealand                 | New Zealand Inventory                                                  | No                     |
| Philippines                 | Philippine Inventory of Chemicals and Chemical Substances (PICCS)      | No                     |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory                          | No                     |

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision**

**Issue date** 03-09-2016

**Revision date** 09-21-2018

**Version #** 02

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