1. Identification

Product identifier: Corticotropin

Other means of identification:
- Catalog number: 1149004

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

- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway, Rockville, MD 20852-1790, US
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- E-mail: RSTECH@usp.org
- Emergency phone number: CHEMTREC within US & Canada 1-800-424-9300, CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards:
- Skin corrosion/irritation: Category 1B
- Serious eye damage/eye irritation: Category 1
- Sensitization, respiratory: Category 1
- Sensitization, skin: Category 1

OSHA hazard(s): Not classified.

Label elements

Signal word: Danger

Hazard statement: Causes severe skin burns and eye damage. May cause an allergic skin reaction. Causes serious eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement

Prevention: Do not breathe dust. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. Contaminated work clothing must not be allowed out of the workplace.

Response: Immediately call a poison center/doctor. If swallowed: Rinse mouth. Do NOT induce vomiting. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical advice/attention. If inhaled: Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor. In eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Storage: Store locked up.

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

Hazard(s) not otherwise classified (HNOC): Not classified.

3. Composition/information on ingredients

Mixture
4. First-aid measures

Inhalation: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin contact: Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact: Rinse with water. Get medical attention if irritation develops and persists.

Ingestion: Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed: Corrosive effects. May cause allergic skin reaction. May cause allergic respiratory reaction.

Indication of immediate medical attention and special treatment needed: Provide general supportive measures and treat symptomatically. For mild/moderate allergic reactions, administer antihistamines with or without inhaled beta agonists, corticosteroids, or epinephrine. For severe allergic reaction, administer oxygen, antihistamines, epinephrine, or corticosteroids. Monitor ECG. (Medi-text)

General information: 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

Suitable extinguishing media: Use fire-extinguishing media appropriate for surrounding materials. Water. Dry chemical or CO2.

Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical: No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters: Wear suitable protective equipment.

Fire-fighting equipment/instructions: Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods: Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling: 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.

Conditions for safe storage, including any incompatibilities: 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

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

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic acid (CAS 64-19-7)</td>
<td>PEL</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 ppm</td>
</tr>
</tbody>
</table>
### US. NIOSH: Pocket Guide to Chemical Hazards

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic acid (CAS 64-19-7)</td>
<td>REL</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 ppm</td>
</tr>
<tr>
<td></td>
<td>STEL</td>
<td>37 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 ppm</td>
</tr>
</tbody>
</table>

### US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic acid (CAS 64-19-7)</td>
<td>STEL</td>
<td>15 ppm</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>10 ppm</td>
</tr>
</tbody>
</table>

**Biological limit values**

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

**Appropriate engineering controls**

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Skin protection**

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Hand protection**

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

**Other**

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

**Respiratory protection**

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Thermal hazards**

Not available.

**General hygiene considerations**

Handle in accordance with good industrial hygiene and safety practice.

### 9. Physical and chemical properties

**Appearance**

White solid.

**Physical state**

Solid.

**Form**

Solid.

**Odor**

Not available.

**Odor threshold**

Not available.

**pH**

Not available.

**Melting point/freezing point**

Not available.

**Initial boiling point and boiling range**

Not available.

**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 in water  Not available.
Partition coefficient (n-octanol/water)  Not available.
Auto-ignition temperature  Not available.
Decomposition temperature  Not available.
Viscosity  Not available.
Other information
  Chemical family  Single chain polypeptide.

10. Stability and reactivity
Reactivity  No reactivity hazards known.
Chemical stability  Material is stable under normal conditions.
Possibility of hazardous reactions  No dangerous reaction known under conditions of normal use.
Conditions to avoid  None known.
Incompatible materials  Strong oxidizing agents.
Hazardous decomposition products  Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information
Information on likely routes of exposure
  Ingestion  Based on available data, the classification criteria are not met.
  Inhalation  Due to lack of data the classification is not possible.
  Skin contact  Causes severe skin burns. May cause an allergic skin reaction.
  Eye contact  Causes serious eye damage.
Symptoms related to the physical, chemical, and toxicological characteristics  Burning pain and severe corrosive skin damage. Permanent eye damage including blindness could result. Skin rash. Irritability. Skin discoloration. Shortness of breath. Swelling of feet or lower legs. Excessive hair growth. Dry skin.
Cross sensitivity  Persons sensitive to one corticosteroid may be sensitive to this material also.
Acute toxicity
Components  Species  Test Results
Acetic acid (CAS 64-19-7)  
  Acute  
  Dermal
    LD50  Rabbit  1060 mg/kg
    Inhalation
    LC50  Guinea pig  5000 mg/l, 1 Hours
  Oral
    LD50  Mouse  5620 mg/l, 1 Hours
           Rat  11.4 mg/l, 4 Hours
    Skin corrosion/irritation  Causes severe skin burns and eye damage.
    Serious eye damage/eye irritation  Causes serious eye damage.
Local effects  
  Acetic acid  Eye irritancy test
    Result: Severe irritation and corneal damage.
    Species: Rabbit
Local effects
Acetic acid

Skin irritancy test
Result: Corrosion.
Species: Rabbit

Respiratory sensitization
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitization
May cause an allergic skin reaction.

Germ cell mutagenicity
Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

Mutagenicity
Acetic acid
Assays in S. typhimurium and E. coli
Result: Negative.
Clastogenicity study in Chinese hamster ovary cells
Result: Negative.
Sister chromatid exchange assay in human peripheral lymphocytes
Result: Negative.

Carcinogenicity
Due to lack of data the classification is not possible.

Reproductive toxicity
Due to lack of data the classification is not possible.

Specific target organ toxicity - single exposure
Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure
Due to lack of data the classification is not possible.

Aspiration hazard
Based on available data, the classification criteria are not met.

12. Ecological information
Ecotoxicity

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic acid (CAS 64-19-7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute Fish</td>
<td>LC50</td>
<td>Oncorhynchus mykiss &gt; 1000 mg/l, 96 hours</td>
</tr>
<tr>
<td>Aquatic Crustacea</td>
<td>EC50</td>
<td>Water flea (Daphnia magna) 65 mg/l, 48 hours</td>
</tr>
<tr>
<td>Aquatic Fish</td>
<td>LC50</td>
<td>Bluegill (Lepomis macrochirus) 75 mg/l, 96 hours</td>
</tr>
</tbody>
</table>

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

Bioaccumulative potential
Not available.

Mobility in soil
Not available.

Other adverse effects
Not available.

13. Disposal considerations
Disposal instructions
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.

Local disposal regulations
Not available.

Hazardous waste code
Not available.

Waste from residues / unused products
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).

Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information
DOT
UN number UN1759
UN proper shipping name Corrosive solids, n.o.s. (CORTICOTROPIN)
Transport hazard class(es) 8
Subsidiary class(es) Not available.
Packing group II

IATA
UN number UN1759
UN proper shipping name Corrosive solid, n.o.s. (CORTICOTROPIN)
Transport hazard class(es)  8
Subsidiary class(es) -
Packaging group II
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

15. Regulatory information

US federal regulations
One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard categories
Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No
SARA 302 Extremely hazardous substance No
SARA 311/312 Hazardous chemical No

Other federal regulations
Safe Drinking Water Act (SDWA) Not regulated.
Food and Drug Administration (FDA) Not regulated.

US state regulations
This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDISL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

Material name: Corticotropin

USP SDS US
6504 Version #: 03 Revision date: 04-22-2015 Issue date: 04-06-2009
Country(s) or region | Inventory name | On inventory (yes/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)

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

| Issue date | 04-06-2009 |
| Revision date | 04-22-2015 |
| Version # | 03 |

Further information: Not available.

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Revision Information: This document has undergone significant changes and should be reviewed in its entirety.