1. Identification

Product identifier: Enflurane

Other means of identification:

- Catalog number: 1235809
- Chemical name: Ethane, 2-chloro-1-(difluoromethoxy)-1,1,2-trifluoro-, (+)-

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:

- Acute toxicity, inhalation: Category 4
- Serious eye damage/eye irritation: Category 2A
- Specific target organ toxicity, single exposure: Category 3 narcotic effects

OSHA hazard(s): Not classified.

Label elements:

- Signal word: Warning
- Hazard statement: Harmful if inhaled. Causes serious eye irritation. May cause drowsiness or dizziness.
- Precautionary statement:
  - Prevention: Use only outdoors or in a well-ventilated area. Avoid breathing vapors. Wash thoroughly after handling. Wear protective gloves. Wear eye/face protection.
  - Response: If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a poison center/doctor/medical professional. If eye irritation persists: Get medical advice/attention.
  - Storage: Store in a well-ventilated place. Keep container tightly closed. Store locked up.
  - Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Not classified.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Hazardous components</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enflurane</td>
<td></td>
<td></td>
<td>13838-16-9</td>
<td>100</td>
</tr>
</tbody>
</table>
4. First-aid measures

**Inhalation**
Move to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Call a POISON CENTER or doctor/physician if you feel unwell.

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

**Eye contact**
Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

**Ingestion**
Rinse mouth. Get medical advice/attention if you feel unwell.

**Most important symptoms/effects, acute and delayed**
Irritation of eyes and mucous membranes. Vapors have a narcotic effect and may cause headache, fatigue, dizziness and nausea.

**Indication of immediate medical attention and special treatment needed**
Do not induce vomiting. Perform gastric lavage. For hypotension, infuse 10-20 mL/kg isotonic fluid. Administer dopamine or norepinephrine if hypotension persists. For bradycardia, administer atropine intravenously. For respiratory distress, administer oxygen and assist ventilation. For malignant hyperthermia, administer 100% oxygen and dantrolene sodium, and reduce body temperature with external cooling methods, if needed. For acidosis, administer sodium bicarbonate. For hyperkalemia, administer 100% oxygen, bicarbonate, glucose, and insulin. For bronchospasm, administer albuterol. For seizures, administer benzodiazepine intravenously. (Poisindex) (Meditext) Provide general supportive measures and treat symptomatically.

**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**
Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

**Unsuitable extinguishing media**
Not available.

**Specific hazards arising from the chemical**
Not applicable.

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

**Fire-fighting equipment/instructions**
As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods**
Cool containers exposed to flames with water until well after the fire is out.

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. Avoid inhalation of vapors. Ensure adequate ventilation. Wear appropriate personal protective equipment.

**Methods and materials for containment and cleaning up**
Absorb spillage with suitable absorbent material. For waste disposal, see section 13 of the SDS. Wash spill site.

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. Use of a designated area is recommended for handling of potent materials.

**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**

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enflurane (CAS 13838-16-9)</td>
<td>Ceiling</td>
<td>2 ppm</td>
<td>Waste anesthetic gas</td>
</tr>
</tbody>
</table>

**US. ACGIH Threshold Limit Values**

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enflurane (CAS 13838-16-9)</td>
<td>TWA</td>
<td>75 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 aerosol-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**

**Hand 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.

**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**

Clear, colorless, volatile liquid.

**Physical state**

Liquid.

**Form**

Liquid.

**Odor**

Mild, sweet odor.

**Odor threshold**

Not available.

**pH**

Not available.

**Melting point/freezing point**

Not available.

**Initial boiling point and boiling range**

131.9 - 135.5 °F (55.5 - 57.5 °C)

**Flash point**

> 200.00 °F (> 93.33 °C) (PMCC)

**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**

30.26 kPa at 25 °C

174.5 - 175 mm Hg at 20 °C

**Vapor density**

1.9

**Relative density**

Not available.

**Solubility in water**

Slightly soluble.

**Partition coefficient (n-octanol/water)**

2.1

**Auto-ignition temperature**

Not available.

**Decomposition temperature**

Not available.

**Viscosity**

Not available.

**Other information**

**Chemical family**

Linear aliphatic derivative.

**Molecular formula**

C3H2ClF5O
Molecular weight 184.49
Percent volatile 100 %
Solubility (other) Miscible with organic solvents, with fats, and with oils.
Specific gravity 1.516 - 1.52

10. Stability and reactivity
Reactivity No reactivity hazards known.
Chemical stability Stable at normal conditions.
Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.
Conditions to avoid Avoid temperatures exceeding the flash point.
Incompatible materials Peroxides. Oxidizers.
Hazardous decomposition products F-. Cl-. 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 Vapors have a narcotic effect and may cause headache, fatigue, dizziness and nausea. Harmful if inhaled.
Skin contact Due to lack of data the classification is not possible.
Eye contact Causes serious eye irritation.

Symptoms related to the physical, chemical, and toxicological characteristics


Cross sensitivity Persons sensitive to one halogenated hydrocarbon anesthetic may be sensitive to this material also.


Acute toxicity Harmful if inhaled.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enflurane (CAS 13838-16-9) Inhalation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>Mouse</td>
<td>81000 ppm, 3 hr</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>14000 ppm, 3 hr</td>
</tr>
<tr>
<td>Oral LD50</td>
<td>Mouse</td>
<td>5 milliliters/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>5450 µliters/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation Due to lack of data the classification is not possible.

Serious eye damage/eye irritation Causes serious eye irritation.

Local effects
Standard Draize Test (100 mg)
Result: Irritant
Species: Rabbit
Organ: Eyes
Severity: Moderate

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Due to lack of data the classification is not possible.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Mutagenicity
In vivo dominant lethal mutaion test in rodents
Result: Negative
In vivo forward gene mutation test in hamster lung cells
Result: Negative
In vivo sister-chromatid exchange test in human lymphocytes
Result: Positive
Carcinogenicity Based on available data, the classification criteria are not met. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Carcinogenicity test
Result: No neoplasm observed.
Species: Mouse

Reproductive toxicity Based on available data, the classification criteria are not met.

Reproductivity
1 % Reproductivity test
Result: Increase in birth defects. There was no increase in birth defects at 0.75 % or less.
Species: Mouse
1.2 % Reproductivity test
Result: Small but statistically significant increase in sperm abnormalities.
Species: Mouse
1.65 % Reproductivity test
Result: No interference with fertility and no adversely affected pregnancy outcomes.
Species: Rat
Reproductivity test
Result: Increase in the incidence of skeletal defects and fetal growth retardation with anesthetic doses.
Species: Rabbit

Specific target organ toxicity - single exposure Narcotic effects.

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

Aspiration hazard
Due to lack of data the classification is not possible.

12. Ecological information
Ecotoxicity Not expected to be harmful to aquatic organisms.

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 This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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. Dispose in accordance with all applicable regulations.

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 UN3334
UN proper shipping name Aviation regulated liquid, n.o.s. (Enflurane)
Transport hazard class(es) 9
Subsidiary class(es) Not available.
Packing group III

IATA
UN number UN3334
UN proper shipping name Aviation regulated liquid, n.o.s. (Enflurane)
Transport hazard class(es) 9
Subsidiary class(es) -
Packing group III

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.
15. Regulatory information

**US federal regulations**
- CERCLA/SARA Hazardous Substances - Not applicable.
- 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 (NDSL)</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>Yes</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>Yes</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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**
- 10-13-2009

**Revision date**
- 07-01-2015

**Version #**
- 04

**Further information**
- Not available.
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Revision Information

Hazard(s) identification: <INDENT>Response
Hazard(s) identification: <INDENT>Disposal
First-aid measures: General information
Physical & Chemical Properties: Multiple Properties
Toxicological information: Symptoms related to the physical, chemical, and toxicological characteristics