SAFETY DATA SHEET

1. Identification

Product identifier: Isoflurane

Other means of identification:
- **Catalog number**: 1349003
- **Chemical name**: Ethane, 2-chloro-2-(difluoromethoxy)-1,1,1-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**:
- Reproductive toxicity: Category 2
- Specific target organ toxicity, single exposure: Category 3 narcotic effects

**OSHA hazard(s)**: Not classified.

Label elements:

- **Signal word**: Warning
- **Hazard statement**: May cause drowsiness or dizziness. 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. Use only outdoors or in a well-ventilated area. Avoid breathing mist or vapor. Wear protective gloves/protective clothing/eye protection/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 exposed or concerned: 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.

**Hazard(s) not otherwise classified (HNOC)**: 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>Isoflurane</td>
<td></td>
<td></td>
<td>26675-46-7</td>
<td>100</td>
</tr>
</tbody>
</table>

Material name: Isoflurane

5550  Version #: 04  Revision date: 08-27-2014  Issue date: 08-07-2007
4. First-aid measures

**Inhalation**
Move to fresh air. For breathing difficulties, oxygen may be necessary. 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**
Rinse with water. Get medical attention if irritation develops and persists.

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

**Most important symptoms/effects, acute and delayed**
Narcotic effects.

**Indication of immediate medical attention and special treatment needed**
Treatment of halogenated hydrocarbon anesthetic overdose may include the following: Induced vomiting is NOT recommended. Perform gastric lavage soon after ingestion (within 1 hour). Administer activated charcoal as a slurry. For circulatory depression or severe hypotension, infuse isotonic fluids and place in Trendelenburg position. If hypotension persists, administer dopamine or norepinephrine. For bradycardia, administer atropine. For respiratory depression, establish a clear airway and administer 100% oxygen. For malignant hyperthermia, administer 100% oxygen and dantrolene sodium, and reduce body temperature with external cooling methods, if needed. For metabolic acidosis, administer sodium bicarbonate. For hyperkalemia, administer oxygen, bicarbonate, and glucose and insulin. For bronchospasms and wheezing, administer a bronchodilator. For seizures, administer a benzodiazepine. If seizures persist, administer phenobarbital or propofol. 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**
Foam. Dry chemical powder. Carbon dioxide (CO2).

**Unsuitable extinguishing media**
Do not use water jet as an extinguisher, as this will spread the fire.

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

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

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 vapors. 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. 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

**Exposure limit values**

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoflurane (CAS 26675-46-7)</td>
<td>TWA</td>
<td>60 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.

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 liquid.

Physical state

Liquid.

Form

Liquid.

Odor

Mildly pungent ethereal odor.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

Not available.

Initial boiling point and boiling range

116.6 - 122 °F (47 - 50 °C)

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

25.06 kPa at 25 °C

295 - 330 mm Hg at 25 °C

Vapor density

6.3

Relative density

Not available.

Solubility in water

Insoluble.

Partition coefficient (n-octanol/water)

2.06

Auto-ignition temperature

Not available.

 Decomposition temperature

Not available.

Viscosity

Not available.

Other information

Chemical family

Linear aliphatic derivative; haloalkane.

Molecular formula

C3H2ClF5O

Molecular weight

184.49
Percent volatile 100 %
Solubility (other) Miscible with common organic solvents, with dehydrated alcohol, with trichloroethylene, with fats, and with oils.
Specific gravity 1.45 - 1.496

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 Peroxides.
Hazardous decomposition products Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. F-. Cl-.

11. Toxicological information
Information on likely routes of exposure
Inhalation
Due to lack of data the classification is not possible. Vapors have a narcotic effect and may cause headache, fatigue, dizziness and nausea.

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

Eye contact
Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics

Delayed and immediate effects of exposure

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

Medical conditions aggravated by exposure

Acute toxicity
<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoflurane (CAS 26675-46-7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50 Mouse</td>
<td>16800 ppm, 3 hr</td>
<td></td>
</tr>
<tr>
<td>LD50 Rat</td>
<td>15300 ppm, 3 hr</td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50 Mouse</td>
<td>5080 microliters/kg</td>
<td></td>
</tr>
<tr>
<td>LD50 Rat</td>
<td>4.77 ml/kg</td>
<td></td>
</tr>
</tbody>
</table>

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

Serious eye damage/eye irritation
Due to lack of data the classification is not possible.

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

Mutagenicity
Bacterial mutation test
Result: Negative
Sister-chromatid exchange test in hamster ovary cells
Result: Negative

Carcinogenicity
Due to lack of data the classification is not possible. IARC: Group 3; this material is not classifiable as to its carcinogenicity in humans. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Reproductive toxicity
Suspected of damaging fertility or the unborn child. For halogenated hydrocarbon anesthetics: Some epidemiological studies have shown higher than normal incidences of miscarriage following exposure.

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
No ecotoxicity data noted for the ingredient(s).

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
Dispose of in accordance with local regulations. 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. (Isoflurane)
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. (Isoflurane)
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.

DOT; IATA

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. 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

<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>No</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 (NDSSL)</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>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</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: 08-07-2007
Revision date: 08-27-2014
Version #: 04
Further information: Not available.

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