

Issuing Date: 09/18/2014

Revision Date: 10/16/2014

**1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING****Product Identifier**

**MSDS Number:** 1087151  
**Product Name:** Isoflurane, USP

**Other means of identification**

**Product Codes:** NDC 10019-360-40, NDC 10019-360-60, NDC 10019-360-96, NDC 10019-360-64, NDC 10019-773-40, NDC 10019-773-60, NDC 13985-030-40, NDC 13985-030-60

**Synonyms:**

Forane  
Isoflurane  
Aerrane  
1-chloro-2,2,2-trifluoroethyl difluoromethyl ether  
Isorrane  
Isovet

**Recommended use of the chemical and restrictions on use**

**Product Use:** Anesthetic.  
**Product Type:** Regulated Prescription Drug  
**Uses advised against:** No information available

**Details of the supplier of the safety data sheet**

BAXTER HEALTHCARE CORPORATION  
DEERFIELD, ILLINOIS 60015  
(800) 422-9837 or (224) 948-4770

**Emergency telephone number**

Rocky Mountain Poison and Drug Center: USA (888) 990-0996  
OUTSIDE USA (303) 389-1422  
CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743)741-6089

**2. HAZARDS IDENTIFICATION****Classification****OSHA Regulatory Status**

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Serious eye damage/eye Irritation	Category 2B
Reproductive Toxicity	Category 2
Specific Target Organ Toxicity (Repeated Exposure)	Category 2

**Label Elements****Emergency Overview****Warning****Hazard Statements**

Causes eye irritation  
Suspected of damaging fertility or the unborn child  
May cause damage to organs through prolonged or repeated exposure

**Precautionary Statements - Prevention**

Obtain special instructions before use  
 Do not handle until all safety precautions have been read and understood  
 Use personal protective equipment as required  
 Wash face, hands and any exposed skin thoroughly after handling  
 Do not breathe dust/fume/gas/mist/vapors/spray

**Precautionary Statements - Response**

IF exposed or concerned: Get medical advice/attention  
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
 If eye irritation persists: Get medical advice/attention

**Precautionary Statements - Storage**

Store locked up

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**Hazards not otherwise classified (HNOC)****Other Information**

- Causes mild skin irritation

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS-No	Weight %
Isoflurane	26675-46-7	100

### 4. FIRST AID MEASURES

**First Aid Measures**

<b>General Advice:</b>	Treat symptomatically and supportively.
<b>Eye contact:</b>	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.
<b>Skin contact:</b>	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops.
<b>Inhalation:</b>	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
<b>Ingestion:</b>	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

**Most important symptoms and effects, both acute and delayed**

A dose less than that needed to produce anesthesia (approximately 1%) may result in symptoms such as dizziness. See patient package insert in shipping carton for complete information.

**Indication of any immediate medical attention and special treatment needed**

Treat symptomatically. See patient package insert in shipping carton for complete information.

## 5. FIRE-FIGHTING MEASURES

**Suitable extinguishing media:**

Use foam or all purpose dry chemicals to extinguish.

**Specific hazards arising from the chemical**

No information available.

**Special protective equipment for firefighters:**

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures**

Depending on local ventilation, clean-up crews may need to wear a chemical cartridge respirator, with a cartridge for organic vapors. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

**Environmental Precautions**

No information available.

**Methods and material for containment and cleaning up****Methods for Containment:**

Small volumes of liquid anesthetic agents may evaporate readily at normal room temperatures, and may dissipate before any clean up attempts are initiated. For large spills, one or more bottles break, ensure adequate ventilation or evacuate area. Large volumes of anesthetic agents may cause sedative effects.

**Methods for cleaning up:**

Restrict persons not wearing protective equipment from areas of spills or leaks until clean up is complete. Large spills should be absorbed using a sorbent that is designed for clean up of organic chemicals. Spill pillows, vermiculite, and carbon-based sorbents are some suitable materials. Keep in suitable, closed containers for disposal.

## 7. HANDLING AND STORAGE

**Precautions for Safe Handling**

**Technical measures/precautions:** Wash thoroughly after handling.

**Conditions for safe storage, including any incompatibilities**

**Technical measures/conditions:** Keep container tightly closed. Keep in a dry, cool and well-ventilated place. Store between 15-30°C (59 to 86°F).

**Incompatible products:** No special restrictions on storage with other products.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Occupational Exposure Limits****Exposure Limits:**

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Isoflurane 26675-46-7	None	None	None	None	None	None

**Appropriate engineering controls**

**Engineering measures:** Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. Well designed and maintained scavenging system on the anesthesia equipment (combined with a good general room ventilation) is important in limiting the exposures of all personnel.

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

**Eye protection:** Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

**Hand protection:** Use chemical resistant, impervious gloves.

**Skin and body protection:** Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits).

**Respiratory protection:** Personal respiratory protection equipment not typically required if engineering controls are in place. If exposure levels may exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR1910.134 (in the US) or equivalent regulation in other regions.

**9. PHYSICAL AND CHEMICAL PROPERTIES****Information on basic physical and chemical properties**

<b>Physical state:</b>	Liquid
<b>Appearance:</b>	Aqueous solution
<b>Color:</b>	Clear, Colorless.
<b>Odor:</b>	Pungent. Ethereal. Musty.
<b>Odor Threshold:</b>	No information available.
<b>pH:</b>	Not applicable.
<b>Melting point/range:</b>	Not available.
<b>Boiling point/range:</b>	48.5°C (119.3°F)
<b>Flash point:</b>	No information available.
<b>Evaporation rate:</b>	Not available.
<b>Flammability (solid, gas):</b>	No information available.
<b>Flammable limits in air-upper (%):</b>	No information available.
<b>Flammable limits in air-lower (%):</b>	No information available.
<b>Vapor pressure:</b>	238 mmHg at 20°C (68°F)
<b>Vapor Density:</b>	No information available.
<b>Density:</b>	1.496 g/cm <sup>3</sup> at 25°C (72°F)
<b>Solubility:</b>	0.275% in water.
<b>Partition coefficient (n-octanol/water):</b>	Not available.
<b>Autoignition temperature:</b>	No information available.
<b>Decomposition Temperature:</b>	No information available.
<b>Viscosity:</b>	Not available.
<b>Explosive Properties:</b>	No information available.
<b>Oxidizing Properties:</b>	No information available.

**Other Information**

Molecular weight: 184.5 g/mole

## 10. STABILITY AND REACTIVITY

**Reactivity**

No data available

**Chemical Stability**

Stable under recommended storage conditions.

**Possibility of Hazardous Reactions**

Not applicable

**Conditions to Avoid**

Do not freeze.

**Incompatible materials**

Peroxides.

**Hazardous Decomposition Products**

These products are halogenated compounds (hydrochloric and hydrofluoric acids). Phosgene.

## 11. TOXICOLOGICAL INFORMATION

Component	LC50 Inhalation	LD50 Dermal	LD50 Oral
Isoflurane 26675-46-7	58.5 g/m <sup>3</sup> (rat)	-	4770 µL/kg (rat)

**Information on likely routes of exposure**

<b>Inhalation:</b>	Practically non-toxic by inhalation. Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). Respiratory effects (may include shortness of breath, bronchospasms, laryngospasms, respiratory depression). Gastrointestinal effects (may include nausea, upset stomach, loss of appetite). Nervous System effects (may include ataxia, tremor, disturbance of speech, lethargy, headache, dizziness, blurred vision).
<b>Eye contact:</b>	May cause eye irritation.
<b>Skin contact:</b>	May cause skin irritation.
<b>Ingestion:</b>	Practically non-toxic if swallowed. No specific hazards other than therapeutic effects. See inhalation.

**Information on Toxicological Effects**

**Symptoms:** No information available.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

<b>Irritation:</b>	Irritating to eyes. Mild skin irritation.
<b>Corrosivity:</b>	Not classified.
<b>Sensitization:</b>	Not classified.
<b>Mutagenic effects:</b>	Not classified
<b>Carcinogenic effects:</b>	No drug related carcinogenic/tumorigenic effects based on animal data.

Component	ACGIH	IARC	NTP	OSHA

Isoflurane 26675-46-7	-	Group 3	-	-
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**Reproductive toxicity:** No impairment to fertility based on animal data. May be fetotoxic at high doses based on animal data. Epidemiological studies suggest higher than normal incidences of problem pregnancies (particularly spontaneous abortions) among exposed personnel.

**STOT - single exposure:** Not classified.

**STOT - repeated exposure:** Liver.

**Aspiration Hazard:** Not classified.

#### Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document.

ATEmix (oral) 4755690 mg/kg

### 12. ECOLOGICAL INFORMATION

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Isoflurane 26675-46-7	None.	None.	None.	None.

#### Ecotoxicity

No information available

100% of the mixture consists of component(s) of unknown hazards to the aquatic environment

#### Persistence and degradability

No information available.

#### Bioaccumulative potential

No information available

#### Mobility in soil

No information available.

#### Other adverse effects

No information available.

### 13. DISPOSAL CONSIDERATIONS

#### Waste treatment methods

**Waste from residues / unused products:** In accordance with local and national regulations.

**Contaminated Packaging:** In accordance with local and national regulations.

### 14. TRANSPORT INFORMATION

#### DOT

**DOT shipping name:** Aviation regulated liquid n.o.s. (Isoflurane)  
**UN Number:** UN3334  
**DOT Packing Group:** III  
**DOT Hazard class:** 9

## 15. REGULATORY INFORMATION

**U.S. Regulations:****TSCA Inventory List -**

The product is exempt from TSCA, it is FDA Regulated

**OTHER REGULATIONS:**

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Isoflurane 26675-46-7	100	Not Listed	Not Listed	Not Listed	Not Listed

**STATE REGULATIONS:**

Component	California Prop. 65	Minnesota Right-To -Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Isoflurane 26675-46-7	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

**CANADIAN REGULATIONS:****Canada DSL Inventory List -**

This product does not comply with DSL

## 16. OTHER INFORMATION

**This data sheet contains changes from the previous version in section(s)?:**

New GHS format.

**Additional information:**

Not Available.

**Prepared by:**

Baxter Research &amp; Development

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To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

**End of Safety Data Sheet**