

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**

General Advice:	Treat symptomatically and supportively.
Eye contact:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.
Skin contact:	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion:	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**

Physical state:	Liquid
Appearance:	Aqueous solution
Color:	Clear, Colorless.
Odor:	Pungent. Ethereal. Musty.
Odor Threshold:	No information available.
pH:	Not applicable.
Melting point/range:	Not available.
Boiling point/range:	48.5°C (119.3°F)
Flash point:	No information available.
Evaporation rate:	Not available.
Flammability (solid, gas):	No information available.
Flammable limits	No information available.
in air-upper (%):	
Flammable limits	No information available.
in air-lower (%):	
Vapor pressure:	238 mmHg at 20°C (68°F)
Vapor Density:	No information available.
Density:	1.496 g/cm ³ at 25°C (72°F)
Solubility:	0.275% in water.
Partition coefficient	Not available.
(n-octanol/water):	
Autoignition temperature:	No information available.
Decomposition Temperature:	No information available.
Viscosity:	Not available.
Explosive Properties:	No information available.
Oxidizing Properties:	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 ³ (rat)	-	4770 µL/kg (rat)

Information on likely routes of exposure

Inhalation:	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).
Eye contact:	May cause eye irritation.
Skin contact:	May cause skin irritation.
Ingestion:	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

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

Component	ACGIH	IARC	NTP	OSHA
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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 components(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 & 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