1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
Isoflurane, USP

Synonyms
1-chloro-2,2,2-trifluoroethyl difluoromethyl ether; 2-Chloro-2-(difluoromethoxy)-1,1,1-trifluoroethane

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Isoflurane

Chemical Formula
C₃H₂ClF₅O

| Component   | Approximate Percent by Weight | CAS Number  | RTECS Number
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Isoflurane</td>
<td>100</td>
<td>26675-46-7</td>
<td>KN6799000</td>
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3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
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<tbody>
<tr>
<td>Isoflurane</td>
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<td>Not Listed</td>
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Emergency Overview
Isoflurane, USP is liquid that is vaporized and used clinically for the induction and maintenance of general anesthesia. Inspired concentrations of 1.5 to 3% isoflurane (15,000 ppm to 30,000 ppm) usually produce surgical anesthesia in 7 to 10 minutes. In the workplace, this material should be considered potentially irritating to the eyes. Based on clinical use, possible target organs include the central nervous system, the respiratory system, gastrointestinal system and the cardiovascular system.

Occupational Exposure Potential
Information on the absorption of this product via ingestion or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms
No signs or symptoms from occupational exposure are known. This material in an anesthetic agent. During clinical use, adverse events have included respiratory depression, headaches, incoordination, nausea, slow heart rate, sedation sleep, drowsiness, dizziness, hyperthermia, vomiting, shivering and breathing difficulty. Cardiovascular effects may include arrhythmias, hypotension, and chest pain. Respiratory effects may also include shortness of breath, bronchospasms, and laryngospasms.

Medical Conditions
Pre-existing sensitivity to this material or to other halogenated agents; pre-existing known or
4. FIRST AID MEASURES

Eye contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability
None anticipated for this product.

Fire & Explosion Hazard
None anticipated for this product.

Extinguishing media
As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures
No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
Small spills of this liquid anesthetic may evaporate quickly at normal room temperatures before any clean up is possible. In the event of a large spill, isolate area around spill. Make sure area has adequate ventilation. Put on suitable protective clothing and protective equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling
No special handling required under conditions of normal product use.

Storage
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions
No special precautions required for hazard control.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m³</th>
<th>ppm</th>
<th>µg/m³</th>
<th>Note</th>
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<tr>
<td>Isoflurane</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None Established</td>
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</table>

**Respiratory protection**

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols or vapors is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N99 or equivalent) with an organic vapor cartridge is recommended under conditions where airborne aerosol or vapor concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin protection**

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

**Eye protection**

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls**

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

- **Appearance/Physical State**: Liquid
- **Color**: Clear, colorless
- **Odor**: Mildly pungent, musty, ethereal odor
- **Odor Threshold**: NA
- **pH**: NA
- **Melting point/Freezing point**: NA
- **Initial Boiling Point/Boiling Point Range**: 48.5°C at 760 mm Hg
- **Evaporation Rate**: NA
- **Flammability (solid, gas)**: NA
- **Upper/Lower Flammability or Explosive Limits**: NA
- **Vapor Pressure**: 238 at 20°C; 295 at 25°C; 367 at 30°C; 450 at 35°C
- **Vapor Density**: 6.4
- **Specific Gravity**: 1.496 at 25°C
- **Solubility**: NA
- **Partition coefficient: n-octanol/water**: NA
- **Auto-ignition temperature**: NA
- **Decomposition temperature**: NA
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10. STABILITY AND REACTIVITY

Reactivity
Not determined. Isoflurane does not decompose in the presence of soda lime, (at normal operating temperatures), and does not attack aluminum, tin, brass, iron or copper.

Chemical Stability
Stable under standard use and storage conditions. Isoflurane contains no additives and has been demonstrated to be stable at room temperature for periods in excess of five years.

Hazardous Reactions
Not determined

Conditions to avoid
Not determined

Incompatibilities
Not determined

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), fluorine and chlorine.

Hazardous Polymerization
Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
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<tr>
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<td>100</td>
<td>LC50</td>
<td>Inhalation</td>
<td>15,300/3H</td>
<td>ppm</td>
<td>Rat</td>
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<tr>
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<td>Oral</td>
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<td>Mouse</td>
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Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce irritation.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product.

Reproductive Effects
Isoflurane has been shown to have a possible anesthetic-related fetotoxic effect in mice when given in doses 6 times the human dose. FDA Pregnancy Category C.

Mutagenicity
No information for product.

Carcinogenicity
Swiss ICR mice were given isoflurane to determine whether such exposure might induce neoplasia. Isoflurane was given at 1/2, 1/8 and 1/32 MAC for
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four in-utero exposures and for 24 exposures to the pups during the first nine weeks of life. The mice were killed at 15 months of age. The incidence of tumors in these mice was the same as in untreated control mice, which were given the same background gases, but not the anesthetic.

Target Organ Effects

Based on clinical use, possible target organs include the central nervous system, the respiratory system, gastrointestinal system and the cardiovascular system.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity
Not determined for product.

Persistence/Biodegradability
Not determined for product.

Bioaccumulation
Not determined for product.

Mobility in Soil
Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal
All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal
Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS: Not regulated
IMDG STATUS: Not regulated
ICAO/IATA STATUS: Regulated
Proper Shipping Name: Aviation Regulated Liquids, N.O.S. (isoflurane)
Hazard Class: 9
UN number: UN3334
Packing group: N/A
Reportable Quantity: N/A
Transport Comments: None

15. REGULATORY INFORMATION

USA Regulations

<table>
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<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
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</table>
Product Name: Isoflurane, USP

RCRA Status: Not Listed
U.S. OSHA Classification: Possible Eye Irritant
Target Organ Toxin

GHS Classification: *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class: Not Applicable
Hazard Category: Not Applicable
Signal Word: Not Applicable
Symbol: Not Applicable
Hazard Statement: Not Applicable
Response: 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 attention. Wash hands after handling.
Get medical attention if you feel unwell

EU Classification:
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Isoflurane.

Classification(s): Not Applicable
Symbol: Not Applicable
Indication of Danger: Not Applicable
Risk Phrases: Not Applicable
Safety Phrases: S23 - Do not breathe vapor.
S24/25 - Avoid contact with skin and eyes.
S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:
ACGIH TLV American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS Chemical Abstracts Service Number
CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT US Department of Transportation Regulations
EEL Employee Exposure Limit
IATA International Air Transport Association
LD50 Dosage producing 50% mortality
NA Not applicable/Not available
NE Not established
NIOSH National Institute for Occupational Safety and Health
OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit
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Prop 65  California Proposition 65
RCRA    US EPA, Resource Conservation and Recovery Act
RTECS   Registry of Toxic Effects of Chemical Substances
SARA    Superfund Amendments and Reauthorization Act
STEL    15-minute Short Term Exposure Limit
TSCA    Toxic Substance Control Act
TWA     8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 10/11/2011
Obsolete Date: 08/26/2009

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