MATERIAL SAFETY DATA SHEET

Product Name: Halothane, USP

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  
Halothane, USP

Synonyms  
2-bromo-2-chloro-1,1,1-trifluoroethane

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name  
Halothane

Chemical Formula  
C₂HBrClF₃

Preparation  
Halothane, USP is stabilized with thymol 0.01% (w/w).

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Halothane</td>
<td>100</td>
<td>151-67-7</td>
<td>KH6550000</td>
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</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Halothane</td>
<td>3</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview  
Halothane, USP is liquid that when vaporized is used clinically for the induction and maintenance of general anesthesia. Anesthesia may be induced with 2 to 4% v/v (20,000 to 40,000 ppm) of halothane in oxygen; it takes up to about 5 minutes to attain surgical anesthesia. In the workplace, this material should be considered potentially irritating to the eyes and a potential occupational reproductive hazard. Based on clinical use, possible target organs include the central nervous system, cardiovascular system, respiratory system, heart, liver, uterus and in rodents, the reproductive system.

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

Signs and Symptoms  
None known from occupational exposures. In clinical use, halothane anesthesia progressively depresses respiration. There may be tachypnea with reduced tidal volume and alveolar ventilation. Halothane anesthesia reduces the blood pressure and frequently decreases the pulse rate. Halothane anesthesia also causes dilation of the vessels of the skin and skeletal muscles. Cardiac arrhythmias may occur during Halothane anesthesia; these include nodal rhythm, A-V dissociation, ventricular extra systoles and asystole. Halothane sensitizes the myocardial
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conduction system to the action of epinephrine and levarterenol (norepinephrine), and the combination may cause serious cardiac arrhythmias. Halothane anesthesia increases cerebral spinal fluid pressure and produces moderate muscular relaxation. Other adverse reactions have included hepatic necrosis, cardiac arrest, hypo-tension, respiratory arrest, cardiac arrhythmias, hyperpyrexia, shivering, nausea and emesis.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to the material and/or similar materials; pre-existing central nervous system, cardiovascular, respiratory, or hepatic ailments.

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. Halothane is nonflammable.

Fire & Explosion Hazard
None anticipated for this product. Halothane vapors mixed with oxygen in proportions from 0.5 to 50% (v/v) are not explosive.

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 fire fighting 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. Halothane should not be kept indefinitely in vaporizer bottles not specifically designed for its use. It is recommended that vaporizers be emptied at the end of each operating day.

**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>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Halothane</td>
<td>ACGIH 8 Hr TLV</td>
<td>404 ppm, 50 mg/m³, N/A µg/m³</td>
</tr>
</tbody>
</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**

Pleasant sweet odor

**Odor Threshold:**

33 ppm

**pH:**

NA

**Melting point/Freezing point:**

NA

**Initial Boiling Point/Boiling Point Range:**

49°C to 51°C at 760 mm Hg

**Evaporation Rate:**

NA

**Flammability (solid, gas):**

NA

**Upper/Lower Flammability or Explosive Limits:**

NA

**Vapor Pressure:**

243 mm Hg at 20°C

**Vapor Density:**

NA

**Specific Gravity:**

1.872 to 1.877 at 20°C

**Solubility:**

NA

**Partition coefficient: n-octanol/water:**

The olive oil/water coefficient is 220 at 37°C
Product Name: Halothane, USP

Auto-ignition temperature: NA
Decomposition temperature: NA

10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined.

Conditions to avoid
Not determined.

Incompatibilities
When moisture is present, the vapor attacks aluminum, brass and lead, but not copper. Rubber, some plastics, and similar materials are soluble in Halothane; such materials will deteriorate rapidly in contact with Halothane vapor or liquid.

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, chlorine, and bromine.

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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<tbody>
<tr>
<td>Halothane</td>
<td>100</td>
<td>LC50</td>
<td>Inhalation</td>
<td>29,000</td>
<td>ppm</td>
<td>Rat</td>
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<tr>
<td></td>
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<td>120,000</td>
<td>mg/m3/4H</td>
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<td>98,000</td>
<td>mg/m3/2H</td>
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<td>340,575</td>
<td>mg/m3/30Min</td>
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<td>270,662</td>
<td>mg/m3/60Min</td>
<td>Mouse</td>
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<tr>
<td>Halothane</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>5680</td>
<td>mg/kg</td>
<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6000</td>
<td>mg/kg</td>
<td>Guinea Pig</td>
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</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product. Vapor concentrations within anesthetic range are nonirritating and have a pleasant odor.

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

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. Halothane was reported to be a severe eye irritant in rabbits. Inadvertent contact of this product with eyes may produce irritation.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product.
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Reproductive Effects
The effects of maternal treatment with halothane during pregnancy at doses in the range of human occupational exposure have been studied in mice and rats, but the results are not entirely consistent. In most studies, such exposure does not cause fetal malformations or death, although an increased frequency of developmental delay and skeletal variants sometimes occurred at doses just below the anesthetic range.

Mutagenicity
Halothane did not induce mutations in Salmonella typhimurium and did not induce chromosomal aberrations in rat bone-marrow cells in vivo. However, dominant lethal effects were observed in two of three studies in male mice.

Carcinogenicity
Halothane was tested for carcinogenicity by inhalation in mice and rats. When mice were exposed in utero and then three times weekly for 78 weeks at the maximum tolerated dose or 24 times at several dose levels, no treatment-related neoplasm was observed. No carcinogenic effect was seen in rats exposed to a low level of halothane alone or in combination with nitrous oxide.

Target Organ Effects
Based on clinical use, possible target organs include the central nervous system, cardiovascular system, respiratory system, heart, liver, uterus and in rodents, the reproductive 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. (halothane)

Hazard Class: 9

UN number: UN3334

Packing group: N/A

Reportable Quantity: N/A

Transport Comments: None
Product Name: Halothane, USP

15. REGULATORY INFORMATION

<table>
<thead>
<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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<td>Halothane</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Listed</td>
</tr>
</tbody>
</table>

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

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:

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

MSDS Coordinator: Hospira GEHS  
Date Prepared: 09/26/2011  
Obsolete Date: 10/18/2007  

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