



A Pfizer Company

SAFETY DATA SHEET

Revision date: 29-Dec-2016

Version: 1.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Isoflurane, liquid for inhalation (Hospira, Inc.)

Trade Name: Not established

Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as anesthetic agent

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Specific target organ systemic toxicity (single exposure): Category 3

Label Elements

Signal Word: Warning

Hazard Statements: H336 - May cause drowsiness and dizziness

Precautionary Statements:

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P271 - Use only outdoors or in a well-ventilated area
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P312 - Call a POISON CENTRE/doctor/physician if you feel unwell
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

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Other Hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Isoflurane	26675-46-7	247-897-7	STOT SE 3 (H336)	100

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions Aggravated by Exposure:** Individuals who have shown hypersensitivity to this material and individuals with heart conditions and impaired kidney and/or liver functions may be more susceptible to toxicity in cases of overexposure.

Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** May reduce blood pressure. Treat symptomatically.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

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Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Combustion may produce hydrogen fluoride, other fluorinated products, oxides of carbon, and other irritating or toxic gases. May include oxides of chlorine. May include hydrogen chloride.

Fire / Explosion Hazards: Not flammable. Fine particles (such as mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Ensure adequate ventilation. Personnel must wear appropriate protective equipment (see Section 8). Prevent exposure by any route.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Prevent discharge to drains.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel. Provide adequate ventilation. Contain the source of the spill or leak and shut off all electrical equipment if it is safe to do so. Use absorbant material to wipe up spill and place in a sealed container for disposal. Clean spill area thoroughly. Prevent runoff from entering waterways or sewers. Prevent discharge to drains.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product used as anesthetic agent

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Isoflurane

Pfizer OEL TWA-8 Hr:	60 ppm
Austria OEL - MAKs	10 ppm
	80 mg/m ³
Czech Republic OEL - TWA	15 mg/m ³
Denmark OEL - TWA	5 ppm
	38 mg/m ³

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Estonia OEL - TWA	10 ppm 80 mg/m ³
Finland OEL - TWA	10 ppm 77 mg/m ³
Ireland OEL - TWAs	50 ppm 380 mg/m ³
Latvia OEL - TWA	2 ppm 20 mg/m ³
Lithuania OEL - TWA	10 ppm 80 mg/m ³
Poland OEL - TWA	32 mg/m ³
Slovakia OEL - TWA	80 mg/m ³
Slovenia OEL - TWA	80 mg/m ³
Spain OEL - TWA	50 ppm 383 mg/m ³
Sweden OEL - TWAs	10 ppm 80 mg/m ³
Switzerland OEL -TWAs	10 ppm 77 mg/m ³

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Clear, colorless
Odor:	Mild Ethereal	Odor Threshold:	No data available.
Molecular Formula:	C ₃ H ₂ ClF ₅ O	Molecular Weight:	184.49
Solvent Solubility:	Soluble: Common organic solvents		
Water Solubility:	Slightly Soluble: Water		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		

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9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point (°C): 48.5C / 119.3F
Partition Coefficient: (Method, pH, Endpoint, Value)
Isoflurane
No data available
Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): 32 kPa @ 20C/68F; 295 - 330 mm Hg @ 25C/77F
Vapor Density (g/ml): 6.3 Heavier than air
Relative Density: 1.45 g/cm³ (bulk density)
Specific Gravity: 1.496 @ 25C/77F
Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	Non-flammable
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	14.5

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties have not been thoroughly investigated. The information included in this section describes the potential hazards of the active ingredient.

Short Term: Anesthetic drug; may cause central nervous system and cardiovascular system effects
Breathing high vapor concentrations may cause central nervous system (CNS) depression resulting in dizziness, light-headedness, headache, nausea, and loss of coordination.
Continued inhalation may result in unconsciousness and death.

Long Term: may have the potential to produce effects on the developing fetus.

Known Clinical Effects: Adverse effects associated with therapeutic use include respiratory depression, headache, nausea, slow heart rate (bradycardia), sedation, sleepiness (somnia), dizziness, shivering, vomiting, irregular heartbeat (cardiac arrhythmia), decrease in blood pressure (hypotension), chest pain, shortness of breath (dyspnea).

Acute Toxicity: (Species, Route, End Point, Dose)

Isoflurane

Rat Oral LD50 4770 mg/kg
Mouse Oral LD50 5080 mg/kg
Rat Inhalation LC50 15,300 ppm (3 hrs)
Mouse Inhalation LC50 16,800 ppm (3 hrs)

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11. TOXICOLOGICAL INFORMATION

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Isoflurane

9 Week(s) Mouse Inhalation 0.5 (MTC) % NOAEL No effects at maximum dose

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Isoflurane

Reproductive & Fertility-Females Mouse Inhalation 0.4 % NOAEL No effects at maximum dose

Reproductive & Fertility-Males Mouse Inhalation 0.4 % NOAEL No effects at maximum dose,

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Isoflurane

Bacterial Mutagenicity (Ames) Negative

Chromosome Aberration Negative

Carcinogen Status:

Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential:

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

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Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

IATA / ICAO

IATA UN / ID No: UN3334
IATA Proper shipping name: Aviation regulated liquid, n.o.s. (isoflurane)
IATA Hazard Class: 9
IATA Packing Group: III

IMDG IMDG

IMDG UN / ID No: Not regulated

ADR/RID

ADR / RID UN / ID No: Not regulated

DOT DOT / ANTT:

DOT Proper shipping name: Not regulated

TDG (Canada):

TDG UN / ID No: Not regulated

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Isoflurane

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	247-897-7

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; H336 - May cause drowsiness and dizziness

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Reasons for Revision: New data sheet.

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Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet