

Product Name: Isoflurane
Issued: Feb-24-2012



SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Isoflurane
Chemical Name: 1-Chloro-1-(difluoromethoxy)-2,2,2-trifluoroethane
Synonyms: Forane: Forene: Isoflurane liquid: Isoflurane: Isoflurane USP: 1-Chloro-2,2,2-trifluoroethyl difluoromethyl ether
List Number: 5260: B506
Drug Code Number: 38765

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended use: General inhalation anaesthetic

1.3 Details of the supplier of the safety data sheet

Supplier: Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064
USA
E-mail Address: Abbott.SDS@abbott.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

Specific target organ systemic toxicity (single exposure) Category 3

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Risk Phrases: R67 - Vapors may cause drowsiness and dizziness

2.2 Label elements

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Section 2. Hazards identification



Signal Word: Warning

Hazard Statements: H336 - May cause drowsiness or 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 to fresh air and keep at rest in a position comfortable for breathing
P312 - Call a POISON CENTER or doctor/physician if you feel unwell
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Isoflurane 26675-46-7	100	247-897-7	R67	STOT SE 3 (H336)	No data available

For the full text of the R-phrases mentioned in this Section, see Section 16
For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1 Description of 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.

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

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: None known from occupational exposure. Clinical data suggests the following: headaches, incoordination, nausea, slow heart rate, sedation, sleep, drowsiness, dizziness, hyperthermia, vomiting, breathing difficulty. Very rare instances of allergic reactions.

Medical Conditions Aggravated by Exposure: Data suggest any pre-existing ailments in the following organs: central nervous system, cardiovascular system, gastrointestinal system, respiratory system. Hypersensitivity to the material and/or similar materials.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Maintain ventilation, electrolyte balance and monitor cardiovascular function, as necessary.

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Thermal decomposition products include - Carbon oxides (COx) Hydrogen fluoride Hydrogen Chloride (HCl).

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: If spill response is required, supplied air respirators with impervious gloves and clothing should be worn by response personnel..

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Material evaporates very rapidly. Evacuate the area of the spill immediately and provide ventilation until the applicable exposure levels are below those described in Section 8.

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6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin, eyes and clothing. Avoid breathing vapors or mists. Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

Recommended use: General inhalation anaesthetic

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Abbott EEL	Skin Notation
Isoflurane 26675-46-7	60 ppm (450 mg/m ³) TWA	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Isoflurane 26675-46-7				50 ppm (TWA) 380 mg/m ³ (TWA) 50 ppm (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Isoflurane 26675-46-7		383 mg/m ³ (TWA)	77 mg/m ³ (TWA) 616 mg/m ³ (STEL)	150 ppm (STEL) 1149 mg/m ³ (STEL) 150 ppm (STEL) 50 ppm (TWA) 383 mg/m ³ (TWA)

8.2. Exposure controls

Engineering Controls: Anesthetic gas scavenging systems should be used during typical product application. Handle inside a process enclosure or chemical fume hood during manufacturing or laboratory use.

Respiratory Protection: If engineering controls are in place, respirators are generally not required during normal conditions of use.

Eyes: Eye protection not required during typical product use conditions. Wear eye protection appropriate to exposures during manufacturing/laboratory use.

Gloves: Impervious gloves.

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Other PPE Data: Wear appropriate body coverings if contact may occur.
Environmental Exposure Controls: Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Clear Colorless Liquid
Odor: Mild, pungent, musty, ethereal odor.
Odor Threshold: Not determined
pH: Not determined.
Boiling Pt. @ 760 mm Hg (°C): 48.5
Melting/Freezing Point (°C): Not determined
Flash Point (°C): Not determined.
Evaporation Rate at 20°C: Not determined.
Flammability (Solid): Not expected to be flammable in air.
Lower Explosive Limit: 14.5 (in 100% oxygen)
Upper Explosive Limit: Not determined.
Vapor Pressure (mm Hg): 295 - 330 at 25 deg. C
Vapor Density (Air = 1): 6.3
Bulk Density at 20°C: 1.45
Specific Gravity: 1.496 @ 25 deg C
Solubility(ies): Soluble in: organic solvents. Slightly soluble in: water.
Partition coefficient: n-octanol/water Not determined.
Autoignition Temp. (°C): Not determined.
Decomposition temperature (°C): Not determined.
Viscosity (centipoise): Not determined.
Explosion Severity: Not determined.
Oxidizer Properties: Not determined.

9.2. Other information

Min. Ignition Energy-Cloud (mJ): > 5000 (no ignition)

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

Self-Heating Tendency: No exotherms seen below 300 deg C in ARC testing.

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10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Strong bases, Alkaline metals.

10.6 Hazardous decomposition products

When heated to decomposition it emits:, Hydrogen fluoride, Hydrogen chloride, Carbon oxides

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Not determined.
Dermal: Not determined.
Inhalation: Clinical Route

Acute Toxicity - Oral: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Isoflurane 26675-46-7	LD50 =	4770 5080	mg/kg	Mice Rats

Acute Toxicity - Dermal: Not determined.

Acute Toxicity - Inhalation: Data for component (s) given below.

Chemical Name	Test	Value	Units	Species
Isoflurane 26675-46-7	LC 50 =	15,300 16,800	ppm	Rats Mice

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: A similar material is an eye irritant.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: In clinical use target organ effects include: central nervous system.

Reproductive Effects: Not determined.

Carcinogenicity: Not determined.

Mutagenicity: Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Isoflurane 26675-46-7	No Data.	Negative	No Data.	Negative

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Aspiration hazard: Not determined

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Not determined.

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

Section 14. Transport information

ICAO/IATA

Status: Regulated

- 14.1. UN Number:** UN3334
14.2. Proper shipping name: Aviation regulated liquid, n.o.s. (1-Chloro-1-(difluoromethoxy)-2,2,2-trifluoroethane)
14.3. Hazard class: 9
14.4. Packing group: III

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14.5. Environmental hazard: Not applicable
14.6. Special Provisions: A27
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

ADR, DOT, IMDG/IMO

Status: Not regulated

14.1. UN Number: Not applicable
14.2. Proper shipping name: Not applicable
14.3. Hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable

Section 15. Regulatory Information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Isoflurane 26675-46-7	247-897-7	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Isoflurane 26675-46-7	-	-	-	-	-	HSR003785

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
ISHL - Japan Industrial Safety and Health Law
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Isoflurane	100	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Isoflurane	100	No	Not Applicable	Not applicable

Immediate Health: Yes
Delayed Health: No
Fire: No

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Sudden Pressure: No
Reactivity: No
RCRA Status: Not determined.
Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.
WHMIS Hazard Class: Not determined.
NFPA Rating:
Health: 2
Fire: 1
Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Risk Phrases: R67 - Vapors may cause drowsiness and dizziness
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