

**Product Name:** Enflurane  
**Issued:** May-21-2014



## **SAFETY DATA SHEET**

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

#### **1.1 Product Identifier**

**Product Name:** Enflurane  
**Chemical Name:** 2-Chloro-1-(difluoromethoxy)-1,1,2-trifluoroethane  
**Synonyms:** Ethrane: Inhalthran  
**Trade name:** Ethrane  
**List Number:** 9406  
**Drug Code Number:** 27388: 27393: 19730

#### **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:** AbbVie Inc.  
1 North Waukegan Road  
North Chicago, IL 60064  
USA  
+1-847-932-7900  
**Customer Service Telephone:** 1-800-255-5162 (US and Canada only)  
+1-847-937-7433  
**E-mail Address:** AbbVie.SDS@abbvie.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**

**General Note** AbbVie

**Skin corrosion/irritation** Category 2  
**Serious eye damage/eye irritation** Category 2  
**Specific target organ systemic toxicity (single exposure)** Category 3

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## Section 2. Hazards identification

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

**Indication of danger:** Xi - Irritant

**Risk Phrases:** R36/37/38 - Irritating to eyes, respiratory system and skin

### 2.2 Label elements



**Signal Word:** Warning

**Hazard Statements:**  
H315 - Causes skin irritation  
H319 - Causes serious eye irritation  
H335 - May cause respiratory irritation  
H336 - May cause drowsiness or dizziness

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention  
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water  
P332 + P313 - If skin irritation occurs: Get medical advice/attention  
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

### 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.
Enflurane 13838-16-9	100	Present	Xi; R36/37/38	STOT SE 3 (H335) (H336) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	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**

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## **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.

**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: hyperthermia, muscle weakness, decreased blood pressure, fast heart rate, nausea, vomiting, respiratory depression, elevated white blood cells. Reported to cause the following: cognitive dysfunction, psychological impairment, memory lapse.

**Medical Conditions Aggravated by Exposure:** No medical conditions aggravated by occupational exposure are known. Data suggest any pre-existing ailments in the following organs: central nervous system, cardiovascular system, respiratory system, liver. Hypersensitivity to the material and/or similar materials.

### **4.3 Indication of any immediate medical attention and special treatment needed**

**Notes To Physician:** Monitor respiratory function, maintaining ventilation with pure oxygen, 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:** Avoid inhalation of combustion products.

### **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**

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### **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.

### **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**

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:**

<b>Chemical Name</b>	<b>Employee Exposure Limit</b>	<b>Skin Notation</b>
Enflurane 13838-16-9	566 mg/m <sup>3</sup> (75ppm)	None

<b>Chemical Name</b>	<b>ACGIH TLV</b>	<b>France</b>	<b>German MAK</b>	<b>Ireland</b>	<b>Italy</b>
Enflurane 13838-16-9	566 mg/m <sup>3</sup> (75 ppm)		150 mg/m <sup>3</sup> TWA	380 mg/m <sup>3</sup> (TWA)	

<b>Chemical Name</b>	<b>The Netherlands</b>	<b>Spain</b>	<b>Switzerland</b>	<b>UK OEL/MEL</b>
Enflurane 13838-16-9		575 mg/m <sup>3</sup> (TWA)	77 mg/m <sup>3</sup> (TWA) 616 mg/m <sup>3</sup> (STEL)	1149 mg/m <sup>3</sup> (STEL) 383 mg/m <sup>3</sup> (TWA)

### **8.2. Exposure controls**

<b>Product Name:</b>	<b>Enflurane</b>
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<b>Engineering Controls:</b>	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.
<b>Respiratory Protection:</b>	An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.
<b>Eyes:</b>	Wear eye protection appropriate to handling activities.
<b>Gloves:</b>	Impervious gloves.
<b>Other PPE Data:</b>	Wear appropriate body coverings if contact may occur.
<b>Environmental Exposure Controls:</b>	Not determined

## Section 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

<b>Appearance:</b>	Clear Colorless Liquid
<b>Odor:</b>	Characteristic odor
<b>Odor Threshold:</b>	Not determined
<b>pH:</b>	Not determined.
<b>Boiling Pt. @ 760 mm Hg (°C):</b>	56.5
<b>Melting/Freezing Point (°C):</b>	Not determined
<b>Flash Point (°C):</b>	Not determined.
<b>Evaporation Rate at 20°C:</b>	Not determined.
<b>Flammability (Solid):</b>	Non-flammable.
<b>Lower Explosive Limit:</b>	Not determined.
<b>Upper Explosive Limit:</b>	Not determined.
<b>Vapor Pressure (mm Hg):</b>	174.5 at 20 deg. C
<b>Vapor Density (Air = 1):</b>	Not determined.
<b>Specific Gravity:</b>	1.516 - 1.159at 25 deg. C
<b>Solubility(ies):</b>	Soluble in: organic liquids, including fats and oils. Slightly soluble in: water.
<b>Partition coefficient: n-octanol/water</b>	Not determined.
<b>Autoignition Temp. (°C):</b>	Not determined.
<b>Decomposition temperature (°C):</b>	Not determined.
<b>Viscosity (centipoise):</b>	Not determined.
<b>Explosion Severity:</b>	Not determined.
<b>Oxidizer Properties:</b>	Not determined.

### 9.2. Other information

Not determined

## Section 10. Stability and reactivity

### 10.1. Reactivity

Not determined

### 10.2. Chemical stability

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Stable under normal conditions

### **10.3. Possibility of hazardous reactions**

**Hazardous reactions:** Not determined.

### **10.4. Conditions to avoid**

Not determined.

### **10.5 Incompatible materials**

Not determined

### **10.6 Hazardous decomposition products**

Heating or fire can release toxic gas

## **Section 11. Toxicological information**

### **11.1. Information on toxicological effects**

#### **Routes of Exposure:**

**Oral:** Unlikely  
**Dermal:** Yes  
**Inhalation:** Clinical Route

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

Chemical Name	Acute Test	Value	Units	Species
Enflurane 13838-16-9	LD50 =	5000-5450	mg/kg	Rats Mice

**Acute Toxicity - Dermal:** Not determined.

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

Chemical Name	Test	Value	Units	Species
Enflurane 13838-16-9	LC 50 =	8100 - 31,500	ppm, 1-4 hours	Animals

**Other Toxicology Data:** Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Enflurane 13838-16-9	LD50 (ip) = LD50 (sc) =	3900 - 6000 19,500 - 38,800	mg/kg	Mice Rats	None.

**Corrosivity:** Not determined.

**Dermal Irritation:** May be a skin irritant.

**Eye Irritation:** Active Ingredient : Produced mild to moderate eye irritation in rabbits.

**Sensitization:** Not determined.

**Toxicokinetics/Metabolism:** Not determined.

**Target Organ Effects:** May cause drowsiness or dizziness

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**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
Enflurane 13838-16-9	No Data.	Negative with activation Negative without activation	No Data.	No Data.

**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.

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## Section 14. Transport information

### ICAO/IATA, DOT

**Status:** Regulated

**14.1. UN Number:** UN3334

**14.2. Proper shipping name:** Aviation regulated liquid, n.o.s. (2-Chloro-1-(difluoromethoxy)-1,1,2-trifluoroethane)

**14.3. Hazard class:** 9

**14.4. Packing group:** III

**14.5. Environmental hazard:** Not applicable

**14.6. Special Provisions:** Not applicable

**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:** Not applicable

### ADR, IMDG/IMO

**Status:** Not regulated

## 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
Enflurane 13838-16-9	Present	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Enflurane 13838-16-9	-	-	-	X	Present	

#### 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:
Enflurane	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):
Enflurane	100	No	Not Applicable	Not applicable



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**Immediate Health:** Yes  
**Delayed Health:** No  
**Fire:** No  
**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: 1  
Fire: 0  
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:** R36/37/38 - Irritating to eyes, respiratory system and skin

**Full text of H-Statements referred to under sections 2 and 3**

H315 - Causes skin irritation, H319 - Causes serious eye irritation, H335 - May cause respiratory irritation, H336 - May cause drowsiness or dizziness

**Document Authored By:** Occupational and Environmental Toxicology

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