

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: Inhelthran
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:

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

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

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

8.2. Exposure controls

Product Name:	Enflurane
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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:	An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.
Eyes:	Wear eye protection appropriate to handling activities.
Gloves:	Impervious gloves.
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:	Characteristic odor
Odor Threshold:	Not determined
pH:	Not determined.
Boiling Pt. @ 760 mm Hg (°C):	56.5
Melting/Freezing Point (°C):	Not determined
Flash Point (°C):	Not determined.
Evaporation Rate at 20°C:	Not determined.
Flammability (Solid):	Non-flammable.
Lower Explosive Limit:	Not determined.
Upper Explosive Limit:	Not determined.
Vapor Pressure (mm Hg):	174.5 at 20 deg. C
Vapor Density (Air = 1):	Not determined.
Specific Gravity:	1.516 - 1.159 at 25 deg. C
Solubility(ies):	Soluble in: organic liquids, including fats and oils. 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

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 decompostion 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
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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

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