

**Product Name:** Sevoflurane  
**Issued:** May-07-2014



## **SAFETY DATA SHEET**

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

#### **1.1 Product Identifier**

**Product Name:** Sevoflurane  
**Chemical Name:** 1,1,1,3,3,3-Hexafluoro-2-(fluoromethoxy) propane  
**Synonyms:** Ultane; Sevorane; Sevoflurano; 1,1,1,3,3,3-Hexafluoro-2-(fluoromethoxy) propane; Fluoromethyl-2,2,2-trifluoro-1-(trifluoromethyl) ethyl ether  
**Trade name:** Ultane  
**List Number:** 4456  
**Drug Code Number:** 74341; 98009

#### **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

**Manufacturer European:** AbbVie Inc.  
via Pontina, km 52  
Campoverde - LT 04010  
Italia

**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**

**Reproductive toxicity** Category 2  
**Specific target organ systemic toxicity (single exposure)** Category 3

**Product Name:** Sevoflurane  
**Issued:** May-07-2014

## Section 2. Hazards identification

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

**Risk Phrases:** R62 - Possible risk of impaired fertility  
R67 - Vapors may cause drowsiness and dizziness

### 2.2 Label elements



**Signal Word:** Warning

**Hazard Statements:** H336 - May cause drowsiness or dizziness  
H361 - Suspected of damaging fertility or the unborn child

P202 - Do not handle until all safety precautions have been read and understood  
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P271 - Use only outdoors or in a well-ventilated area  
P281 - Use personal protective equipment as required  
P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing  
P308 + P313 - IF exposed or concerned: Get medical advice/attention

### 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.
Sevoflurane 28523-86-6	100	NA	R62 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

**Product Name:** Sevoflurane  
**Issued:** May-07-2014

**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:** Clinical data suggests the following: headaches, incoordination, nausea, breathing difficulty. slow heart rate, sedation, sleep, drowsiness, dizziness, Very rare instances of allergic reactions.

**Medical Conditions Aggravated by Exposure:** Data suggest any pre-existing ailments in the following organs: central nervous 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:** 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**

#### **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**

**Product Name:** Sevoflurane  
**Issued:** May-07-2014

**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**

Avoid contact with skin, eyes and clothing. 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>
Sevoflurane 28523-86-6	60 ppm (500 mg/m <sup>3</sup> ) TWA	None

### **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:** 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

**Product Name:** Sevoflurane  
**Issued:** May-07-2014

## **Section 9. Physical and chemical properties**

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

<b>Appearance:</b>	Clear Colorless Liquid
<b>Odor:</b>	Ethereal odor.
<b>Odor Threshold:</b>	Not determined
<b>pH:</b>	7.0 - 7.5
<b>Boiling Pt. @ 760 mm Hg (°C):</b>	58.6
<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>	Not flammable in air.
<b>Lower Explosive Limit:</b>	> 25%
<b>Upper Explosive Limit:</b>	Not determined.
<b>Vapor Pressure (mm Hg):</b>	245.5at 30 deg C
<b>Vapor Density (Air = 1):</b>	6.94
<b>Specific Gravity:</b>	1.525
<b>Solubility(ies):</b>	Slightly soluble in: water. Miscible with ethanol, ether, benzene, chloroform.
<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**

**Min. Ignition Energy-Cloud (mJ):** > 5000

## **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.

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

Not determined.

### **10.5 Incompatible materials**

Alkaline metals., Strong bases

**Product Name:** Sevoflurane  
**Issued:** May-07-2014

**10.6 Hazardous decomposition products**

Carbon oxides, Hydrogen fluoride

**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
Sevoflurane 28523-86-6	LD50 =	10,800	mg/kg	Rats
		18,200		Mice
		10.8 - 16.6	ml/kg	Rats
		18.2 - 24.3		Mice

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

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

Chemical Name	Test	Value	Units	Species
Sevoflurane 28523-86-6	LC 50 =	28,800	ppm	Rats
		28,300 - 83,000		Mice
		106,000		Rabbits
		73,000		Dog
		68,000		Monkey

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

Chemical Name	Test Type	Value	Units	Species	Comments
Sevoflurane 28523-86-6	LD50 (ip) =	6.3 - 7.4	ml/kg	Rats	
		10.5 - 11.7		Mice	

**Corrosivity:** Not determined.

**Dermal Irritation:** Not determined.

**Eye Irritation:** Produced mild to moderate eye irritation in animals.

**Sensitization:** Not determined.

**Toxicokinetics/Metabolism:** Not determined.

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

**Reproductive Effects:** In animals adverse reproductive effects include: maternal toxicity, reduced fertility in males, reduced fertility in females, reduced fetal growth, fetal abnormalities. Based on these experimental results, protection against maternal toxicity will provide adequate protection against potential embryo-fetal toxicity and teratogenicity

**Carcinogenicity:** Not determined.

**Mutagenicity:** Data for component (s) given below.

**Product Name:** Sevoflurane  
**Issued:** May-07-2014

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Sevoflurane 28523-86-6	Negative	Negative	Negative	Negative

**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

Data for component (s) given below.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Sevoflurane 28523-86-6	100	43	Fathead Minnow	96 Hours

Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Sevoflurane 28523-86-6	100	48	Daphnia magna	48 Hours

Chemical Name	Percent	EB 50/ErC 50 (mg/l)	Species	Duration
Sevoflurane 28523-86-6	100	>100	Pseudokirchneriella subcapitata	72 Hours

### 12.2. Persistence and degradability

Not readily biodegradable.

Data for component (s) given below.

Chemical Name	Percent	% Degradation	Duration
Sevoflurane 28523-86-6	100	4.4	28 days

### 12.3. Bioaccumulative potential

Data for components given below.

Chemical Name	Percent	Log Po/w
Sevoflurane 28523-86-6	100	1.75

### 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

**Product Name:** Sevoflurane  
**Issued:** May-07-2014

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. (1,1,1,3,3,3-Hexafluoro-2-(fluoromethoxy) propane)  
**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, DOT

**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
Sevoflurane 28523-86-6	-	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Sevoflurane 28523-86-6	-	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



**Product Name:** Sevoflurane  
**Issued:** May-07-2014

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:
Sevoflurane	100	Not Listed	Not Listed	Non répertorié

**SARA 313 Information**

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

**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:** R62 - Possible risk of impaired fertility, R67 - Vapors may cause drowsiness and dizziness

**Full text of H-Statements referred to under sections 2 and 3**  
H336 - May cause drowsiness or dizziness, H361 - Suspected of damaging fertility or the unborn child

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

**Issued:** May-07-2014

**Product Name:** Sevoflurane  
**Issued:** May-07-2014

**Supersedes the SDS dated:** Feb-17-2012

**Disclaimer:**

*The information and recommendations contained herein are based upon tests believed to be reliable. However, AbbVie Inc. does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. AbbVie Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.*