

Product Name: Sevoflurane
Issued: Oct-05-2017

abbvie
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

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2.2. Label elements



Signal Word: Warning

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

Precautionary Statements 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	Weight-%	EINECS/ELINCS Number	EU - GHS Substance Classification	REACH Reg. No
Sevoflurane 28523-86-6	100	NA	STOT SE 3 (H336) Repro 2 (H361)	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.

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

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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

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.

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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:

Chemical Name	Employee Exposure Limit	Skin Notation
Sevoflurane 28523-86-6	60 ppm (500 mg/m ³) TWA; 10 ppm (80 mg/m ³) for Sweden and Finland; 5 ppm (40 mg/m ³) for Norway and 7 ppm (55 mg/m ³) for Poland	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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Clear Colorless Liquid
Odor: Ethereal odor.
Odor Threshold: Not determined
pH: 7.0 - 7.5
Boiling Pt. @ 760 mm Hg (°C): 58.6
Melting/Freezing Point (°C): Not determined
Flash Point (°C): Not determined

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Evaporation Rate at 20°C:	Not determined
Flammability (Solid):	Not flammable in air.
Lower Explosive Limit:	> 25%
Upper Explosive Limit:	Not determined
Vapor Pressure (mm Hg):	245.5 at 30 deg C
Vapor Density (Air = 1):	6.94
Specific Gravity:	1.525
Solubility(ies):	Slightly soluble in: water. Miscible with ethanol, ether, benzene, chloroform.
Partition coefficient:	Not determined
n-octanol/water	
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

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

10.6. Hazardous decomposition products

Carbon oxides, Hydrogen fluoride

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Unlikely

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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 18,200 10.8 - 16.6 18.2 - 24.3	mg/kg ml/kg	Rats Mice Rats 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 28,300 - 83,000 106,000 73,000 68,000	ppm	Rats Mice Rabbits Dog 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 10.5 - 11.7	ml/kg	Rats 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:

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

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12.1. Toxicity

Data for component (s) given below:

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

Chemical Name	Weight-%	48h EC50 (daphnia - mg/l) (48HLCD)	Species	Duration
Sevoflurane 28523-86-6	100	48	Daphnia magna	48 Hours

Chemical Name	Weight-%	72h IC50 (algae - mg/l) (72HICA)	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	Weight-%	% Degradation	Duration
Sevoflurane 28523-86-6	100	4.4	28 days

12.3. Bioaccumulative potential

Data for components given below.

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

12.4. Mobility in soil

Not determined

12.5. Results of PBT and 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

Product Name: Sevoflurane
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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	4.8 mg/L	4.8 mg/L	4.8 mg/L	Not listed	4.8 mg/L

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Sevoflurane 28523-86-6	4.8 mg/L	Present	4.8 mg/L	4.8 mg/L	4.8 mg/L	

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	Weight-%	NTP:	IARC:	ACGIH:
Sevoflurane	100	Not listed	Not listed	Non répertorié

SARA 313 Information

Chemical Name	Weight-%	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

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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

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