

Product Name:
Issued:

SevoFlo
May-21-2015

SDS #077



ANIMAL HEALTH

SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: SevoFlo

Synonyms: 1,1,1,3,3,3-Hexafluoro-2-(fluoromethoxy) propane; Sevoflurane; Fluoromethyl-2,2,2-trifluoro-1-(trifluoromethyl) ethyl ether

List Number: 5458

Drug Code Number: 74341
98009

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

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: Abbott Animal Health
100 Abbott Park Road
Dept AH52
Blgn AP6C-5
Abbott Park
IL 60064

Customer Service Telephone: 1 - 888 - 299 - 7416 (Abbott Animal Health 8:00 am - 5:00 pm CST)

E-mail Address: Abbott.SDS@abbott.com

1.4 Emergency telephone number

Emergency Telephone: 1 (800) 424-9300 CHEMTREC (USA)
1 (703) 527 3887 CHEMTREC (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
None

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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:
H335 - May cause respiratory irritation
H361 - Suspected of damaging fertility or the unborn child

Precautionary Statements
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P312 - Call a POISON CENTER or doctor/physician if you feel unwell
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P501 - Dispose of contents/container to an approved waste disposal plant

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) Repr. 2 (H361) | No data available |

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

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 the source of exposure. Flush eyes with copious amounts of water. If irritation or redness persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. No known antidote.

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. No known antidote.

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Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Maintain airway, provide oxygen and ventilation. Facilities for circulatory resuscitation must be immediately available. No known antidote.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. No known antidote.

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 measures that are appropriate to local circumstances and the surrounding environment

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: Wear self-contained breathing apparatus and protective suit

Section 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal Precautions: Use personal protective equipment identified in Section 8.

6.2 Environmental precautions

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

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6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Ventilate area. Restrict spill area to those equipped with personal protection specified in Section 8. Wash spill area. Recover product and place in an appropriate container for disposal.

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.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions. Not determined.

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

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 | 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: 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.

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: | Not determined |
| 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. |
| Evaporation Rate at 20°C: | Highly volatile. |
| Flammability (Solid): | Non-flammable. |
| 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 (H2O = 1) |
| Solubility(ies): | Slightly soluble in: water, Miscible with ethanol, ether, chloroform, benzene, Not determined. |
| Partition coefficient: | |
| 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

| |
|---|
| Not determined |
| Min. Ignition Energy-Layer (mJ): |

> 5000

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

10.4. Conditions to avoid

Not determined.

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10.5 Incompatible materials

Alkaline metals, Strong bases

10.6 Hazardous decomposition products

When heated to decomposition it emits:, Carbon dioxide (CO₂), Carbon monoxide (CO), Hydrogen fluoride

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: No
Dermal: Not determined.
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 |
| | | | | |
| | | | | |
| | | | | |

Notes to Toxicologist: Sevoflurane LD50 in dogs = 73,000 - 106,000 ppm.

| 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: 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.

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Reproductive Effects:

In animals adverse reproductive effects include: maternal toxicity, reduced fetal growth, fetal abnormalities.

Carcinogenicity:

Not determined.

Mutagenicity:

Negative in the Ames assay. Negative in the micronucleus test. Negative in the chromosomal aberration assay. Negative in the mouse lymphoma assay.

| 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 | 48h EC50 (daphnia - mg/l) (48LCD) | Species | Duration |
|---------------------------|---------|-----------------------------------|---------------|----------|
| Sevoflurane 28523-86-6 | 100 | 48 | Daphnia magna | 48 Hours |

| Chemical Name | Percent | 72h IC50 (algae - mg/l) (72HICA) | Species | Duration |
|---------------------------|---------|----------------------------------|---------------------------------|----------|
| Sevoflurane 28523-86-6 | 100 | >100 | Pseudokirchneriella subcapitata | 72 Hours |

12.2. Persistence and degradability

Not determined.

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

12.3. Bioaccumulative potential

Not determined

| 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

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 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

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Regulated

14.1. UN Number: UN3334
14.2. Proper shipping name: Aviation regulated liquid,n.o.s. (sevoflurane)
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:

49 CFR – Ship in accordance with 49 CFR dangerous goods requirements

ICAO/IATA – Ship in accordance with ICAO/IATA dangerous goods requirements

IMDG – Ship in accordance with IMDG Code dangerous goods requirements

ADR – Ship in accordance with the ADR dangerous goods requirements

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 |
|---------------|----------------|------|-----|------|-------|
|---------------|----------------|------|-----|------|-------|

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| | | | | | | |
|---------------------------|---|---|---|---|-------------|---|
| 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

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: Not determined.

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

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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 if inhaled

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