Sevoflurane

1) PRODUCT AND COMPANY IDENTIFICATION

Product name: Sevoflurane
Synonyms: Sojourn
CAS Number: 28523-86-6
Formula: C₄H₃F₉O
Chemical Family: Anesthetic, Halogenated Ether
Manufacturer: Piramal Critical Care
3950 Schelden Circle
Bethlehem, PA 18017
24 Hour Emergency Number: CHEMTREC 1-703-527-3887

2) COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>Weight %</th>
<th>Classification</th>
</tr>
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<tbody>
<tr>
<td>Sevoflurane</td>
<td>100</td>
<td>None</td>
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3) HAZARDS IDENTIFICATION

Emergency Overview: CAUTION! Anesthetic Agent. Overexposure by inhalation to the vapors may cause temporary nervous system depression with anesthetic effects such as dizziness, headache, confusion, incoordination, or loss of consciousness, they should be moved to an area of fresh air. Concentrations of anesthetic in the air would have to reach approximately 2-3 % before personnel would be expected to experience significant dizziness. Gross overexposure (> 20%) may possibly alter the heart's electrical activity with irregular pulse, palpitations, or inadequate circulation.

Exposure Routes: Inhalation. Skin contact. Eye contact. Ingestion.

Inhalation: Practically non-toxic by inhalation. Cardiovascular effects may include fluctuations in heart rate, changes in blood pressure, chest pain. Respiratory effects may include shortness of breath, bronchospasms, laryngospasms, respiratory depression. Gastrointestinal effects may include nausea, upset stomach, loss of appetite. Nervous system effects may include ataxia, tremor, disturbance of speech, lethargy, headaches, dizziness, blurred vision.

Skin Contact: May cause skin irritation.

Eye Contact: May cause eye irritation.

Ingestion: Practically non-toxic if swallowed. No specific hazards other than therapeutic effects. See inhalation.

4) FIRST AID MEASURES

Inhalation: If high concentrations are inhaled, immediately remove to fresh air. If not breathing, perform artificial respiration. Keep the affected person warm and at rest. Get medical attention as soon as possible.

Skin Contact: In case of contact, remove contaminated clothing, and wash contaminated skin with soap and water. Seek medical attention if irritation is present.
Eye Contact: In case of contact, immediately wash (irrigate) the eyes with large amounts of tepid potable water, occasionally lifting the lower and upper lids. Get medical attention immediately.

Ingestion: DO NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities are swallowed, get medical attention immediately.

Note to Physician: Due to the possible disturbances of cardiac rhythm, catecholamine drugs, such as epinephrine, should be considered only as a last resort in life-threatening emergencies.

5) FIRE FIGHTING MEASURES
Flash Point: Not determined
Specific Methods: No information available
Flammable Limits in air-lower (%): Not available
Flammable Limits in air-upper (%): Not available
Autoignition: Not available
Extinguishing Media: Use extinguishing media appropriate to surrounding fire conditions
Fire Fighting Instructions: Fire fighters and others should wear NIOSH approved positive pressure self-contained breathing apparatus (SCBA) and turnout gear.
Fire and Explosion Hazard: Use water spray to cool containers. Containers may rupture under fire conditions.

6) ACCIDENTAL RELEASE MEASURES
In Case of Spill or Leak: Small volumes of liquid anesthetic agents may readily evaporate at room temperatures and may dissipate before any clean up attempts are initiated. For large spills, provide adequate ventilation or evacuate area. Large quantities of anesthetic agents may cause sedative effects. Restrict personnel not donning protective equipment from areas of spills or leaks until clean up is complete. A sorbent designed for organic chemicals should be used for large spills. Spill pillows, vermiculite, and carbon-based sorbents are examples of suitable materials. Dike spill and prevent liquid from entering sewers, waterways or low areas. Sweep or scoop up and remove to a suitable container. Close container and dispose of container in accordance with federal, state, and local regulations.

7) HANDLING AND STORAGE
Handling: Wash thoroughly after handling.
Storage: Keep container tightly sealed. Store in a dry, cool, and well ventilated place. Store 20 - 25°C (68 - 77°F). Deviations between 15 - 30°C (59 - 86°F) permitted. [See USP Controlled Room Temperature].

8) EXPOSURE CONTROLS/PERSONAL PROTECTION
Engineering Controls: Investigate engineering techniques, process enclosures or local exhaust ventilation to keep airborne levels below recommended exposure limits.
Eye Protection: Safety glasses, chemical splash goggles, face shield, or other full faced protection should be available for use if potential exists for exposure to splashes.
Skin Protection: Chemical resistant, impervious gloves should be used to avoid prolonged or repeated exposure. Wear a work uniform or laboratory coat. Additional body garments should be used based upon the tasks being performed.
Respiratory Protection: When working with small quantities in a well ventilated area, respiratory protection may not be required. If exposure levels exceed regulatory limits, implement a respiratory protection program that is in compliance with OSHA.
29 CFR1910.134 or equivalent in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive pressure mode.

OSHA-Time Weighted Average: None
OSHA-Short Term Exposure Limit: None
OSHA-Ceiling Limits: None
ACGIH-Time Weighted Average: None
ACGIH-Short Term Exposure Limit: None
ACGIH-Ceiling Limit Value: None
NIOSH REL: Ceiling 2 ppm (60 minutes) recommended exposure limit for halogenated waste anesthetic gas.

9) PHYSICAL AND CHEMICAL PROPERTIES
Physical State: Liquid
Appearance: Clear
Color: Colorless
Odor: Slight ethereal
pH: Neutral
Molecular Weight: 200.05 g/mole
Boiling Point: 58.6°C (137.5°F) at 760 mm Hg.
Vapor Pressure: 157 mm Hg at 20°C (68.8°F)
317 mm Hg at 36°C (96.8°F)
Evaporation Rate: > 1
Water Solubility: Slightly soluble
% Volatile by Volume: 100 WT%

10) STABILITY AND REACTIVITY
Stability: Material is stable under recommended storage conditions.
Incompatibility: Peroxides
Polymerization: Not applicable
Hazardous Decomposition Products: These products are halogenated compounds (e.g., hydrochloric and hydrofluoric acids, phosgene).

11) TOXICOLOGICAL INFORMATION
LD₅₀ 10800 mg/Kg oral-rat
LC₅₀ 28800 ppm/3H inhalation-rat
LD₅₀ 18200 g/Kg oral mouse
LC₅₀ 28500 ppm/3H inhalation-mouse
Acute Toxicity: Cardiovascular effects - may include fluctuation in heart rate, change in blood pressure, chest pain. Respiratory effects - may include shortness of breath, bronchospasms, laryngospasms, respiratory depression.
Gastrointestinal effects - may include nausea, upset stomach, loss of appetite.
Nervous System effects - ataxia, tremor, disturbance of speech, lethargy, headache, dizziness, blurred vision.

Chronic Toxicity: Target Organs- nervous system, heart, liver
Carcinogenic Effects: Not classified or listed by OSHA, IARC, NTP, EU, and ACGIH. No data is available on the product itself.
Mutagenic Effects: Not mutagenic in a standard battery of genetic toxicological tests.
Reproductive Toxicity: Not considered fetotoxic based on animal data. Epidemiological studies suggest higher than normal incidences of problem pregnancies (particularly spontaneous abortions) among exposed personnel.
FDA Pregnancy Category: B
12) ECOLOGICAL INFORMATION
Ecotoxicity Effects: No data available
Bioaccumulation: No data available

13) DISPOSAL CONSIDERATIONS
Waste Disposal: Comply with federal, state, and local regulations in the disposal of waste.

14) TRANSPORT INFORMATION
DOT: Not regulated for inner packagings not exceeding 5.0 L (1.3 gallons) net capacity each. Regulated for inner packagings exceeding 5.0 L (1.3 gallons) net capacity each.
   DOT shipping name: Aviation regulated liquid, N.O.S., (Sevoflurane)
   UN number: UN3334
   Packing Group: None
   DOT hazard class: 9

ICAO/IATA:
   IATA proper shipping name: Aviation regulated liquid, N.O.S., (Sevoflurane)
   IATA UN number: UN3334
   IATA primary hazard class: 9
   IATA packing group: None
   IATA packing instruction: 906

TDG (Canada): Not regulated
IMO/IMDG: Not regulated
ADR/RID: Not regulated

15) REGULATORY INFORMATION
FDA: Regulated
TSCA Inventory List: This product is exempt from TSCA.

16) OTHER INFORMATION
Revised Logo and storage temperature data.

The information above is believed to be accurate and is intended only as a guide. Piramal Critical Care assumes no responsibility for any damages resulting from handling or contact with the above material.