SAFETY DATA SHEET

Sevoflurane, USP

1) PRODUCT AND COMPANY IDENTIFICATION

Product name:	Sevoflurane
Synonyms:	Piramal Sevoflurane™ Fluoromethyl 2,2,2-trifluro-1-(trifluoromethyl) ethyl ether HFFMOP
CAS Number:	28523-86-6
Formula:	$C_4H_3F_7O$
Chemical Family:	Anesthetic, Halogenated Ether
Recommended Use:	Inhalable anesthetic – (Prescription Drug to be Administered by Medical Professionals Only)
Manufacturer:	Piramal Critical Care, Inc 3950 Schelden Circle Bethlehem, PA 18017
Supplier:	Piramal Critical Care, Inc. 3950 Schelden Circle Bethlehem, PA 18017
24 Hour Emergency Number:	CHEMTREC 1-703-527-3887

2) HAZARDS IDENTIFICATION

GHS Classification:

Physical Hazard:	Not classified
Health Hazard:	Skin Irritation – Category 3 Reproductive Toxicity – Category 2 Eye Effects – Category 2A Acute Toxicity (Respiratory) – Category 3 Specific target organ toxicity, single exposure - Category 3 – Narcotic Effects

Label Elements:

Signal Word: Warning

Hazard Statements:
H316 – Causes mild skin irritation
H319 – Causes serious eye irritation
H335 – May cause respiratory irritation
H336 – May cause drowsiness or dizziness
H361 – Suspected of damaging fertility or the unborn child
H373 – May cause damage to organs – repeat exposure

Precautionary Statements:
P202 – Do not handle until all safety precautions have been read and understood
P233 - Keep container tightly closed
P260 – Do not breath vapors
P264 – Wash thoroughly after handling
P271 – Use in well-ventilated area
P314 – Get immediate medical advice if you feel unwell
P501 – Dispose of contents/container to an approved waste disposal site

Classification: Non-Dangerous when shipped via ground or water. Dangerous when shipped via air (see section 14)

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, and 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.

3) COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	Classification	CAS #
Sevoflurane	100	None	28523-86-6

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: Rinse mouth. 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 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 (%): N/A

Flammable Limits in air-upper (%): N/A

Auto ignition: N/A

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.

PPE (Inhalation): Depending on effectiveness of local ventilation, an air purifying respirator with organic vapor cartridge can be used to protect against vapors

7) HANDLING AND STORAGE

Handling: Wash thoroughly after handling.

Storage: Keep container tightly sealed. Store in a dry, cool, and well ventilated place. Store between 15-30 deg C (59-86 deg F).

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

Appearance:	Clear
Physical State:	Liquid
Color:	Colorless
Odor:	Slight ethereal
Odor Threshold:	Not available
pH:	Neutral
Molecular Weight:	200.05 g/mole
Boiling Point:	58.6 deg C (137.5 deg F) at 760 mm Hg.
Melting/Freezing Point:	32 – 77 F (0-25 C)
Vapor Pressure:	157 mm Hg at 20 deg C (68.8 deg F) 197 mm Hg at 25 deg C (77 deg F) 317 mm Hg at 36 deg C (96.8 deg F)
Vapor Density:	6.94
Relative Density:	1.5
Evaporation Rate:	> 1
Water Solubility:	Slightly soluble
% Volatile by Volume:	100 WT%

Specific Gravity:	1.5 (Water 1)
Flash Point:	N/A
Explosive Limits:	N/A
Ignition Temperature:	N/A
Flammability (solid/gas):	Not available
Partition coefficient: **(** n-octanol/water)	Not available
Viscosity:	Not available

10) STABILITY AND REACTIVITY

Stability: Material is stable under recommended storage conditions.
Incompatibility: Peroxides
Polymerization: Not applicable
Hazardous Decomposition Products: Irritating and/or toxic fumes under fire conditions. These products are halogenated compounds (hydrochloric and hydrofluoric acids may be liberated).
Conditions to Avoid: N/A
Hazardous Reactions: N/A

11) TOXICOLOGICAL INFORMATION

LD_{50}	10800 mg/kg oral-rat
LC_{50}	28800 ppm/3H inhalation / rat
LD_{50}	18200 g/kg oral mouse
LC_{50}	28300 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
Degradability:	Not Known
Mobility:	Will preferentially want to partition to air. In water, will settle to bottom following water flow. Turbulence will enhance vaporization.
Atmospheric Effects:	Greenhouse gas

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:	III
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:	III
IATA packing instruction:	964
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.
Poisons Schedule:	Schedule 4
AICS Listing:	Not listed

16) OTHER INFORMATION

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

SDS Updates:
06-06-2017 – New Logo
09-24-2020 – Removed Risk and Safety Phrases