

SAFETY DATA SHEETS

This SDS packet was issued with item:

078912351

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071300912 071300938 071300946 071300953 071300961 078852187 078906595 078906596 078906598 078908197
078913228 078931363

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078887838 078906597 078911833

SAFETY DATA SHEET



Sevoflurane, USP

1) PRODUCT AND COMPANY IDENTIFICATION

Product name:	Sevoflurane
Synonyms:	Piramal Sevoflurane™ Fluoromethyl 2,2,2-trifluoro-1-(trifluoromethyl) ethyl ether HFFMOP
CAS Number:	28523-86-6
Formula:	C ₄ H ₃ F ₇ O
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)

Risk Phrases:

R36/37/38 Irritating to eyes, respiratory system, and skin
R67 Vapors may cause dizziness
R63(Xn) Possible Risk of Harm to the Unborn Child

Safety Phrases:

S2 Keep out of Reach of Children
S3 Keep in a cool place
S7 Keep Container tightly closed
S9 Keep Container in a well-ventilated place
S24/S25 Avoid Contact with Skin and Eyes
S38 In case of insufficient ventilation, Wear Suitable respiratory equipment
S51 Use only in well ventilated areas.

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

<u>Component</u>	<u>Weight %</u>	<u>Classification</u>	<u>CAS #</u>
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

LD₅₀	10800 mg/kg oral-rat
LC₅₀	28800 ppm/3H inhalation / rat
LD₅₀	18200 g/kg oral mouse
LC₅₀	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.
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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

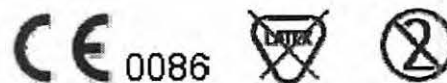
The information above is believed to be accurate and is intended only as a guide. Piramal Inc. assumes no responsibility for any damages resulting from handling or contact with the above material.

SDS Updates:
06-06-2017 – New Logo

Manufactured by	Medline Industries, Inc.									
Made in	Malaysia									
Reference (Sizes 5.5 – 9.0)	MSG1055, MSG1060, MSG1065, MSG1070, MSG1075, MSG1080, MSG1085, MSG1090									
Product Description	Sterile Synthetic Powder-Free Surgical Gloves									
Primary Material	Isolex™ Polyisoprene Rubber (This product does not contain natural rubber latex.)									
Color	White									
Grip/Finish	Smooth									
Donning Lubricant	Synthetic Polyacrylate Resin									
Moisturizing Agent	Aloe Vera									
Chemical Accelerators	Zinc Diethyldithiocarbamate (ZDEC), Zinc Mercaptobenzothiazole (ZMBT)									
Former Design	Anatomical, curved design to replicate natural hand shape and reduce fatigue during use									
Cuff Design	Anti-rolldown, beaded design to reduce cuff-rolldown during use									
Thickness	<table border="0"> <tr> <td><u>Single Wall</u></td> <td><u>Mils</u></td> <td><u>mm</u></td> </tr> <tr> <td>Finger Tip</td> <td>10.0</td> <td>0.25</td> </tr> <tr> <td>Cuff</td> <td>6.5</td> <td>0.16</td> </tr> </table>	<u>Single Wall</u>	<u>Mils</u>	<u>mm</u>	Finger Tip	10.0	0.25	Cuff	6.5	0.16
<u>Single Wall</u>	<u>Mils</u>	<u>mm</u>								
Finger Tip	10.0	0.25								
Cuff	6.5	0.16								

Packaging	100 pairs per case, 25 pairs per dispenser box 100% Polyethylene Peel Pouch
	<ul style="list-style-type: none"> • Prevents tearing when opening product • Protects product from ozone degradation • Ensures product sterility during shelf life

Packaging Dimensions	<u>Carton</u>	<u>Dispenser</u>	<u>Pouch</u>
Length (mm)	290	290	290
Width (mm)	300	150	150
Height (mm)	260	130	1.5
Weight (g)	4780	1195	45



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AQL	1.0
Sterilization	Gamma Radiation
Expiration Date	3 years
Storage Conditions	Store at room temperature. Avoid excessive heat. Keep dry. Product should be shielded from direct sunlight, fluorescent lighting, x-rays, moisture, and ozone.
Regulations & Quality Standards	Manufacturing locations are certified to EN ISO 13485 Product meets requirements of the EU Medical Device Directive 93/42/EEC Product meets requirements of the European standards EN 455-1, EN455 -2, and EN 455-3
Viral Penetration	Tested and passed, in accordance with ASTM F 1671.
EN 455 Test Results	Testing performed by an ISO17025 accredited laboratory.

EN 455-1	Test Results	EN 455 Requirement
Freedom from Holes	Complies	AQL 1.5

EN 455-2	Test Results	EN 455 Requirement
Dimensions (Length)	298 mm (size 7.5)	270 mm (size 7.5)
Dimensions (Width)	95 mm (size 7.5)	95 ± 5 mm (size 7.5)
Force at break before accelerated aging	12.5 Newtons	≥ 9 Newtons
Force at break after accelerated aging (7 days at 70°c in an oven)	11.6 Newtons	≥ 6 Newtons

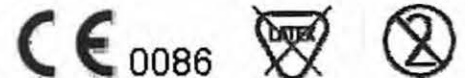
EN 455-3	Test Results	EN 455 Requirement
Powder Content	0.76 mg/glove	< 2.0 mg/glove
Protein Content	N/A	N/A

Manufacturer Information

US HEADQUARTERS **LOCAL CONTACT**
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Corporate Quality Assurance/Regulatory Affairs

September 7, 2017

Subject: Safety Data Sheets

Item Description: [SensiCare with Aloe Powder-Free Surgical Gloves](#)

Item: MSG1055, MSG1055H, MSG1055G, MSG1060, MSG1060H, MSG1060Z, MSG1065, MSG1065H, MSG1065Z, MSG1070, MSG1070H, MSG1070Z, MSG1075, MSG1075H, MSG1075Z, MSG1080, MSG1080H, MSG1080Z, MSG1085, MSG1085H, MSG1085Z, MSG1090, MSG1090H, MSG1090Z

The item(s) referenced above for which you have requested a Safety Data Sheet are manufactured or distributed by Medline Industries, Inc. and are retailed as a medical device, drug, cosmetic or article. Products of this type are not subject to the Hazard Communication Standard (29 CFR 1910.1200). This exemption is set forth in the following sections:

Section b (6) This section does not apply to:

Section b (6) (v) Articles (as that term is defined in paragraph (c) of this section);

Section b (6) (vii) Any drug, as that term is defined in the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies);

Section b (6) (viii) Cosmetics which are packaged for sale to consumers in a retail establishment, and cosmetics intended for personal consumption by employees while in the workplace;

Section b (6) (ix) Any consumer product or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 *et seq.*) and Federal Hazardous Substances Act (15 U.S.C. 1261 *et seq.*) respectively, where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended;

Section b (6) (Xii) Biological hazards.

Section (c) *Definitions. Article* means a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.

These products, in their marketed packaging, are generally not considered hazardous under normal conditions of use when used in accordance with labeling instructions.

Medline Corporate Quality
1-800-MEDLINE (1-800-633-5463)