

SAFETY DATA SHEET

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SECTION 1 – Identification of the Material and Supplier

Product Name	PENTHROX [®] (METHOXYFLURANE)
Product Code(s)	ME-MEOTH, ME-7590-45, ME-MS245, ME-MS246, ME-MS260, ME-759044
Recommended Use	Inhalation analgesic - for pre-hospital pain relief and short surgical procedures
Other Names	2,2-dichloro-1,1-difluoromethoxyethane; 2,2-dichloro-1,1-difluoroethylmethyl ether; Ethane, 2,2-dichloro-1,1-difluoro-1-methoxy; Ether, 2,2-dichloro-1,1-difluoroethyl methyl
Company Name	Medical Developments International Ltd. (ABN 14 106 340 667)
Address	4 Caribbean Drive, Scoresby, Victoria, Australia, 3179
Fax	+61 (3) 9547 0262
Phone	+61 (3) 9547 1888
Emergency Contact	13 11 26 (Poisons Information Centre - 24 hours)
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PENTHROX INHALER

Methoxyflurane must only be administered using the Pentrox Inhaler, a polyethylene tube incorporating a polypropylene wick. Do not exceed recommended dose. The Pentrox Inhaler is a single-patient use device. After use, place used Pentrox Inhaler and bottle in sealed plastic bag and dispose of responsibly through normal waste.

SECTION 2 – Hazards Identification

Hazard Classification	HAZARDOUS SUBSTANCE, NON DANGEROUS GOODS (Classified as Hazardous according to the criteria of NOHSC)
Risk Phrase(s)	R36/37/38 - Irritating to eyes, respiratory system and skin. R67 - Vapours may cause drowsiness and dizziness.
Safety Statement(s)	S24/25 - Avoid contact with eyes and skin. S46 - If swallowed, seek medical advice immediately and show this container or label. S51 - Use only in well-ventilated areas.

SECTION 3 – Composition/Information on Ingredients

Compound/Ingredient	CAS Number	Proportion
Methoxyflurane	76-38-0	>99.9%
Butylated hydroxytoluene (BHT)	128-37-0	0.01%

SECTION 4 – First Aid Measures

Swallowed	DO NOT INDUCE VOMITING. Rinse mouth with water and then give water to drink. Seek immediate medical assistance.
Eye	Immediately irrigate with copious amounts of water for at least 15 minutes. Eyelids to be held open. In all cases of eye contamination it is a sensible precaution to seek medical attention.
Skin	Wash contaminated skin with plenty of soap and water. Remove contaminated clothing and wash before re-use. If irritation occurs seek medical attention.
Inhaled	Fresh air, rest. Refer for medical attention.
First Aid Facilities	Eye wash and normal washroom facilities.
Advice to Doctor	Treat symptomatically.

SECTION 5 – Fire Fighting Measures

Suitable Extinguishing Media	CO ₂ , Powder, Water spray, Foam.
Hazards from Combustion	Carbon Monoxide, Carbon Dioxide, Hydrogen Chloride, Hydrogen Fluoride.
Precautions for fire fighters & special protective Equipment	Wear full protective suit. Wear self-contained breathing apparatus

SECTION 6 – Accidental Release Measures

Emergency Procedures	Alert all nearby personnel of potential Hazard and evacuate area Ensure adequate ventilation before entering affected area Wear protective equipment and clothing Keep unprotected persons away from affected area Remove/Isolate all ignition sources.
Environmental Precautions	Do not allow the material to be released to the environment without proper governmental permits
Methods and Materials for Contamination and Clean up procedures	Absorb with liquid-binding material (sand, diatomite, sawdust, vermiculite). Wear self-contained breathing apparatus. Wear protective equipment and clothing. Dispose of all contaminated material according to local waste legislations.

SECTION 7 – Handling and Storage

Precautions for safe handling	Avoid contact with skin and eyes. Avoid inhalation of vapour or mist. See section 2 for precautions.
Storage Conditions	Store in a tightly closed container. Avoid direct contact with air or light. Keep separated from incompatible substances. Store in a well-ventilated area away from foodstuff. Keep bulk containers closed at all times - check regularly for leaks. This material is a Prescription Only Medicine. Store in accordance with local regulations & standards.

SECTION 8 – Exposure Controls/Personal Protection

National exposure Standards	There is currently no established exposure standard for Methoxyflurane. There are, however, well established standards for Halothane, which is regarded as the most studied of the halogenated inhalational anaesthetic agents. Halothane standards are generally accepted as applicable to all agents in this class, including Methoxyflurane. The threshold limit value (TLV) for Halothane is set at 50 ppm for use as a single agent as stated by the American ACGIH.
Other Exposure Information	An Occupational exposure limit has not been established for methoxyflurane by NIOSH. Human clinical and toxicity data have been independently reviewed and used to derive a

Maximum Exposure Limit (MEL) of 15 ppm.

Engineering Controls

DO NOT enter confined spaces where vapour may have collected. Use in well ventilated areas. Where ventilation is inadequate, local exhaust ventilation should be used. Vapour is heavier than air - prevent concentration in hollows or sumps. Keep containers closed when not in use.

Personal Protective Equipment

FOR BULK HANDLING or SPILL CLEANUP:

RESPIRATOR TYPE: Where ventilation is inadequate, the use of an Air Purifying Respirator with a Type A Organic Vapour filter complying with AS/NZS 1715 and AS/NZS 1716 is recommended.

EYE PROTECTION: Safety glasses or goggles.

GLOVE TYPE: PVA gloves.

CLOTHING: Overalls or similar protective clothing.

SECTION 9 – Physical and Chemical Properties

Appearance	Clear, colourless liquid
Odour	Characteristic odour
pH	Not applicable
Vapour Pressure	2.66 kPa @ 17.7°C
Vapour Density (absolute)	7.36 g/L @ 37°C
Boiling Point	104.6°C
Melting Point	-35°C
Solubility in Water	<1 mg/L @ 19°C
Specific Gravity	1.426 g/ml @ 25°C (water = 1)
Flash Point	63°C (Open Cup method) 38°C (Closed Cup method)
Combustibility Rate	Does not sustain combustibility @75°C for 30 sec.
Flamm. Limit LEL	7%
Flamm. Limit UEL	Not available
Decomposition Temp.	Not Determined
Volatile Component	99.9%
Solubility in Organic	Soluble in acetone, alcohol, chloroform, ether, acetonitrile, oils.
Stability	Stable under normal conditions, may be sensitive to prolonged exposure to light.
Haz. Polymerization	Will not occur.
Materials to Avoid	Oxidising agents and powdered metals.
Formula	C ₃ HOC ₂ F ₂
Molecular Weight	164.97

SECTION 10 – Stability and Reactivity

Chemical Stability

Stable at normal temperatures and pressures.

Conditions to avoid	Avoid heat, flames, sparks and other sources of ignition. Sealed containers may rupture or explode if exposed to high levels of heat. Keep out of water supplies and sewers.
Incompatible materials	Oxidizing materials. Finely powdered metals.
Hazardous decomposition products	Thermal decomposition products: Halogenated compounds, oxides of carbon
Hazardous reactions	Will not polymerize.

SECTION 11 – Toxicological Information

Acute - Swallowed	The liquid may be discomforting to the gastrointestinal tract and may cause nausea and vomiting.
Acute - Eye	The liquid is irritating to the eyes and may cause pain and redness.
Acute - Skin	Prolonged or repeated skin contact with the liquid may cause irritation.
Acute - Inhaled	The vapour may be irritating to the upper respiratory tract. Exposure to low vapour concentrations can cause headache and nausea. (High vapour concentrations, such as when used as an anaesthetic, have a depressant action on the central nervous system producing loss of consciousness.)
Chronic	Chronic inhalation of methoxyflurane in high doses may cause liver and kidney damage. It has been reported that volatile agents may increase the risk of spontaneous abortion. To our knowledge there have been no reported cases of this occurring when methoxyflurane is used as an analgesic. However, during early pregnancy, exposure to any volatile agent should be limited or avoided, as with many medications as a precaution. The presence of other drugs or pre-existing medical conditions may increase the effects of methoxyflurane on the renal system, but only when used in anaesthetic quantities.
Toxicology	Oral (rat): LD50: 3600 mg/kg Inhalation (rat): LC50: 33,500 mg/m ³ /4H Inhalation (human): TCLo: 3,500 ppm/1H Eye (rabbit): 100 mg (moderate irritation)

SECTION 12 – Ecological Information

Ecotoxicity	No data available. Do not allow to access drains or sewers.
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Persistence & Degradability No data available.

Mobility No data available.

SECTION 13 – Disposal Considerations

Dispose of product in accordance with all applicable local and federal regulations. May be subjected to specific disposal regulations.

SECTION 14 – Transport Information

UN Number	IATA-DGR: Non dangerous goods IMDG: Non dangerous goods ADR/RID: Non dangerous goods
UN proper shipping name	IATA-DGR: Non dangerous goods IMDG: Non dangerous goods ADR/RID: Non dangerous goods
Class and Subsidiary Risk	IATA-DGR: Non dangerous goods IMDG: Non dangerous goods ADR/RID: Non dangerous goods
Packaging Group	IATA-DGR: Non dangerous goods IMDG: Non dangerous goods ADR/RID: Non dangerous goods
Special Precautions for user	This material is a Prescription Only Medicine and must be stored, maintained and used in accordance with both local & federal regulations.
Hazchem Code	3Z
Other Information	Methoxyflurane is not a dangerous goods or mixture according to Australian Dangerous Goods Code (Edition 7.3, August 2014 – section 2.3.1.1) and the IATA Dangerous Goods Regulations (54 th Edition, January 2013 – section 3.3.1.3). Liquid meeting the definition of these codes with a flash point of more than 35C which to not sustain combustion need not be considered as flammable liquids for the purpose of this code.

SECTION 15 – Regulatory Information

Regulatory Status of methoxyflurane under relevant Australian health, safety and environmental legislation:

- (a) SUSMP – methoxyflurane is Schedule 4 (Prescription Only Medicine)
- (b) Any applicable prohibition or notification/licensing requirements including for carcinogens under commonwealth, state or territory legislation – none
- (c) Agricultural and Veterinary Chemicals Act 1988 – none
- (d) AICS – listed

This product is classified as Hazardous according to the criteria of NOHSC.

Additional information:

CERCLA/SARA Hazardous Substances: Not applicable.

CERCLA (Superfund) reportable quantity: None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard	Yes
	Delayed Hazard	Yes
	Fire Hazard	Yes
	Pressure Hazard	No
	Reactivity Hazard	No
Section 302 extremely hazardous substance		No
Section 311 hazardous chemical		No

Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes

Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

SECTION 16 – Other Information

Contact Poisons information Centre (24 hours) **Tel: 13 11 26**
Infosafe No. **ACOFS**

IMPORTANT NOTE:

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...End of SDS...