



## SAFETY DATA SHEET

**Issue Date:** March 2001  
**Revision No.:** 9  
**Revision Date:** May 2018

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### SECTION 1 – Product Identifier and Identity for the Chemical

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<b>Product identifier</b>	PENTHROX® ( <i>METHOXYFLURANE</i> )
<b>Other means of identification</b>	
<b>Product Code(s)</b>	ME-MEOTH, ME-7590-45, ME-MS245, ME-MS246, ME-MS260
<b>Chemical Names</b>	2,2-dichloro-1,1-difluoromethoxyethane; 2,2-dichloro-1,1-difluoroethyl methyl ether; Ethane, 2,2-dichloro-1,1-difluoro-1-methoxy; Ether, 2,2-dichloro-1,1-difluoroethyl methyl
<b>Recommended Use</b>	Inhalation analgesic - for pre-hospital pain relief and short surgical procedures
<b>Manufacturer</b>	
<b>Company Name</b>	Medical Developments International Ltd. (ABN 14 106 340 667)
<b>Address</b>	4 Caribbean Drive, Scoresby, Victoria 3179, Australia
<b>Fax</b>	+61 (3) 9547 0262
<b>Phone</b>	+61 (3) 9547 1888
<b>Emergency Contact</b>	<b>13 11 26</b> (Poisons Information Centre - 24 hours)
<b>Infosafe No.</b>	<b>ACOFS</b>

#### **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.

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### SECTION 2 – Hazard Identification

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#### **Classification of the substance or mixture**

Skin corrosion/irritation – Category 2	<b>H315</b>
Serious eye irritation – Category 2A	<b>H319</b>
Specific target organ toxicity (STOT) single exposure – Category 3	<b>H335</b>
Specific target organ toxicity (STOT) single exposure – Category 3	<b>H336</b>

#### **Label elements, including precautionary statements**

<b>Signal word</b>	<b>WARNING</b>
	<b>H315</b> – Causes skin irritation
	<b>H319</b> – Causes serious eye irritation



**H335** – May cause respiratory irritation

**H336** – May cause drowsiness or dizziness

**Precautionary statements**

**P102** – Keep out of reach of children

**P262** – Do not get in eyes, on skin, or on clothing

**P271** – Use only outdoors or in a well-ventilated area

**P301 + P312** – IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

**P302 + P352** – IF ON SKIN: Wash with plenty of soap and water.

**P305 + P351 + P338** – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

**Other Hazards**

Hazardous Substance, Non-dangerous goods (NOHSC)

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## SECTION 3 – Composition/Information on Ingredients

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

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## SECTION 4 – First Aid Measures

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**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.

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## SECTION 5 – Fire Fighting Measures

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**Suitable Extinguishing Media**

CO<sub>2</sub>, Powder, Water spray, Foam.

**Hazards from Combustion**

Carbon Monoxide, Carbon Dioxide, Hydrogen Chloride,

	Hydrogen Fluoride.
<b>Precautions for fire fighters &amp; special protective Equipment</b>	Wear full protective suit. Wear self-contained breathing apparatus

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## SECTION 6 – Accidental Release Measures

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<b>Emergency Procedures</b>	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.
<b>Environmental Precautions</b>	Do not allow the material to be released to the environment without proper governmental permits
<b>Methods and Materials for Contamination and Clean up procedures</b>	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.

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## SECTION 7 – Handling and Storage

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<b>Precautions for safe handling</b>	Avoid contact with skin and eyes. Avoid inhalation of vapour or mist. See section 2 for precautions.
<b>Storage Conditions</b>	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. <b>This material is a Prescription Only Medicine. Store in accordance with local regulations &amp; standards.</b>

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## SECTION 8 – Exposure Controls/Personal Protection

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<b>National exposure Standards</b>	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.
<b>Other Exposure Information</b>	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.

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## SECTION 9 – Physical and Chemical Properties

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<b>Appearance</b>	Clear, colourless liquid
<b>Odour</b>	Characteristic odour
<b>pH</b>	Not applicable
<b>Vapour Pressure</b>	2.66 kPa @ 17.7°C
<b>Vapour Density (absolute)</b>	7.36 g/L @ 37°C
<b>Boiling Point</b>	104.97°C
<b>Melting Point</b>	-35°C
<b>Solubility in Water</b>	<1 mg/L @ 19°C
<b>Specific Gravity</b>	1.420 – 1.425 g/ml @ 25°C (water = 1)
<b>Flash Point</b>	63°C (Open Cup method) 38°C (Closed Cup method)
<b>Combustibility Rate</b>	Does not sustain combustibility @75°C for 30 sec.
<b>Flamm. Limit LEL</b>	7%
<b>Flamm. Limit UEL</b>	Not available
<b>Decomposition Temp.</b>	Not Determined
<b>Volatile Component</b>	99.9%
<b>Solubility in Organic Stability</b>	Soluble in acetone, alcohol, chloroform, ether, acetonitrile, oils. Stable under normal conditions, may be sensitive to prolonged exposure to light.
<b>Haz. Polymerization</b>	Will not occur.
<b>Materials to Avoid</b>	Oxidising agents and powdered metals.
<b>Formula</b>	C <sub>3</sub> H <sub>4</sub> Cl <sub>2</sub> F <sub>2</sub> O
<b>Molecular Weight</b>	164.97

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## SECTION 10 – Stability and Reactivity

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### 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.

<b>Incompatible materials</b>	Oxidizing materials. Finely powdered metals.
<b>Hazardous decomposition products</b>	Thermal decomposition products: Halogenated compounds, oxides of carbon
<b>Hazardous reactions</b>	Will not polymerize.

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## SECTION 11 – Toxicological Information

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<b>Toxicology</b>	<p>Oral (rat): LD50: 3600 mg/kg</p> <p>Inhalation (rat): LC50:33,500 mg/m<sup>3</sup>/4H</p> <p>Inhalation (human): TCLo: 3,500 ppm/1H</p> <p>Eye (rabbit): 100 mg (moderate irritation)</p>
<b>Acute toxicity</b>	Substance has been evaluated and based on available data, does not meet the classification criteria. The liquid may be discomforting to the gastrointestinal tract and may cause nausea and vomiting. 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.)
<b>Skin corrosion/irritation</b>	Prolonged or repeated skin contact with the liquid may cause irritation.
<b>Serious eye damage/irritation</b>	The liquid is irritating to the eyes and may cause pain and redness.
<b>Respiratory or skin Sensitization</b>	Substance has been evaluated and based on available data, does not meet the classification criteria.
<b>Germ cell mutagenicity</b>	Substance has been evaluated and based on available data, does not meet the classification criteria.
<b>Carcinogenicity</b>	Substance has been evaluated and based on available data, does not meet the classification criteria.
<b>Reproductive toxicity</b>	Substance has been evaluated and based on available data, does not meet the classification criteria.
<b>STOT – single exposure</b>	<p>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.</p> <p>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.</p>
<b>STOT – repeated exposure</b>	Substance has been evaluated and based on available data, does not meet the classification criteria.

<b>Aspiration hazard</b>	Substance has been evaluated and based on available data, does not meet the classification criteria.
<b>Information on routes of exposure</b>	Inhalation of vapour.
<b>Symptoms related to Exposure</b>	Causes eye irritation and drowsiness or dizziness. May cause skin and respiratory irritation.
<b>Immediate, delayed and chronic health effects from exposure</b>	No data available.
<b>Exposure levels</b>	No data available.
<b>Interactive levels</b>	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.
<b>Data limitations</b>	No data available.

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## SECTION 12 – Ecological Information.

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<b>Ecotoxicity</b>	No data available. Do not allow to access drains or sewers.
<b>Persistence &amp; Degradability</b>	No data available.
<b>Mobility</b>	No data available.

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## SECTION 13 – Disposal Considerations

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

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## SECTION 14 – Transport Information

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<b>UN Number</b>	IATA-DGR: Non-dangerous goods IMDG: Non-dangerous goods ADR/RID: Non-dangerous goods
<b>UN proper shipping name</b>	IATA-DGR: Non-dangerous goods IMDG: Non-dangerous goods ADR/RID: Non-dangerous goods
<b>Class and Subsidiary Risk</b>	IATA-DGR: Non-dangerous goods IMDG: Non-dangerous goods ADR/RID: Non-dangerous goods
<b>Packaging Group</b>	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<sup>th</sup> 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.

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## SECTION 15 – Regulatory Information

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**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)

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## SECTION 16 – Other Information

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

### IMPORTANT NOTE:

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