MATERIAL SAFETY DATA SHEET

SECTION 1 – Identification of the Material and Supplier

Product Name: PENTHROX® (METHOXYFLURANE)
Product Code(s): ME-MEOHT, ME-7590-45, ME-MS245, ME-MS246, ME-MS260
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)
Infosafe No.: ACOFS

PENTHROX INHALER

Methoxyflurane must only be administered using the Penthrox Inhaler, a polyethylene tube incorporating a polypropylene wick. Do not exceed recommended dose. The Penthrox Inhaler is a single-patient use device. After use, place used Penthrox 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

<table>
<thead>
<tr>
<th>Compound/Ingredient</th>
<th>CAS Number</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methoxyflurane</td>
<td>76-38-0</td>
<td>&gt;99.9%</td>
</tr>
<tr>
<td>Butylated hydroxytoluene (BHT)</td>
<td>128-37-0</td>
<td>0.01%</td>
</tr>
</tbody>
</table>

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**
CO₂, 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.

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**SECTION 9 – Physical and Chemical Properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Clear, colourless liquid</td>
</tr>
<tr>
<td>Odour</td>
<td>Characteristic odour</td>
</tr>
<tr>
<td>pH</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour Pressure</td>
<td>2.66 kPa @ 17.7°C</td>
</tr>
<tr>
<td>Vapour Density (absolute)</td>
<td>7.36 g/L @ 37°C</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>104.6°C</td>
</tr>
<tr>
<td>Melting Point</td>
<td>-35°C</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>&lt;1 mg/L @ 19°C</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.426 g/ml @ 25°C (water = 1)</td>
</tr>
<tr>
<td>Flash Point</td>
<td>63°C (Open Cup method)</td>
</tr>
<tr>
<td></td>
<td>38°C (Closed Cup method)</td>
</tr>
<tr>
<td>Combustibility Rate</td>
<td>Does not sustain combustibility @75°C for 30 sec.</td>
</tr>
<tr>
<td>Flamm. Limit LEL</td>
<td>7%</td>
</tr>
<tr>
<td>Flamm. Limit UEL</td>
<td>Not available</td>
</tr>
<tr>
<td>Decomposition Temp.</td>
<td>Not Determined</td>
</tr>
<tr>
<td>Volatile Component</td>
<td>99.9%</td>
</tr>
<tr>
<td>Solubility in Organic</td>
<td>Soluble in acetone, alcohol, chloroform, ether, acetonitrile, oils.</td>
</tr>
<tr>
<td>Stability</td>
<td>Stable under normal conditions, may be sensitive to prolonged exposure to light.</td>
</tr>
<tr>
<td>Haz. Polymerization</td>
<td>Will not occur.</td>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>Oxidising agents and powdered metals.</td>
</tr>
<tr>
<td>Formula</td>
<td>C₃HOCIC₂F₂</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>164.97</td>
</tr>
</tbody>
</table>

**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 discomfting 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/m³/4H
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.
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 (54th 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)

<table>
<thead>
<tr>
<th>Hazard categories</th>
<th>Immediate Hazard</th>
<th>Delayed Hazard</th>
<th>Fire Hazard</th>
<th>Pressure Hazard</th>
<th>Reactivity Hazard</th>
<th>Section 302</th>
<th>Section 311</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Inventory status

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
</tbody>
</table>
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 No
United States Toxic Substances Control Act (TSCA) Inventory No
& Puerto Rico

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

### SECTION 16 – Other Information

<table>
<thead>
<tr>
<th>Contact</th>
<th>Poisons information Centre (24 hours)</th>
<th>Tel: 13 11 26</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infosafe No.</td>
<td>ACOFS</td>
<td></td>
</tr>
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</table>

**IMPORTANT NOTE:**

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...End of MSDS...