



# MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 1.1

Page 1 of 5

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Trimebutine Maleate Injectable Solution**

**Trade Name:** Debridat®  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as antispasmodic and/or gastric motility regulator.

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Trimebutine maleate	34140-59-5	251-845-9	50 mg/5 mL
Benzyl Alcohol	100-51-6	202-859-9	*

Ingredient	CAS Number	EU EINECS List	%
Sodium chloride	7647-14-5	231-598-3	*
Water for injection	7732-18-5	231-791-2	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Clear, colorless solution  
**Signal Word:** WARNING

**Statement of Hazard:** May cause gastrointestinal system effects

**Additional Hazard Information:**  
**Short Term:**

May cause eye and skin irritation (based on components) The active ingredient is not acutely toxic. Accidental ingestion may cause effects similar to those seen in clinical use. Based on its pharmacologic properties, exposure to this compound may cause effects on the gastrointestinal system.

**Known Clinical Effects:** Adverse effects associated with the therapeutic use of trimebutine are infrequent include skin rash, sleepiness, headache, vomiting, and dizziness

**EU Indication of danger:** Not classified

## MATERIAL SAFETY DATA SHEET

Material Name: Trimebutine Maleate Injectable Solution  
Revision date: 05-Jan-2007

Page 2 of 5  
Version: 1.1

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 4. FIRST AID MEASURES

**Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:** Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

**Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire Fighting Procedures:** Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

**Fire / Explosion Hazards:** Not applicable

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

**General Handling:** Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate ventilation.

**Storage Conditions:** Store in a cool, dry, well-ventilated area. Keep container tightly closed when not in use.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Trimebutine maleate  
Pfizer OEL TWA-8 Hr:

1.0 mg/m<sup>3</sup>

## MATERIAL SAFETY DATA SHEET

Material Name: Trimebutine Maleate Injectable Solution  
Revision date: 05-Jan-2007

Page 3 of 5  
Version: 1.1

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Personal Protective Equipment:**

**Hands:** Wear impervious gloves if skin contact is possible.  
**Eyes:** Safety glasses or goggles  
**Skin:** Wear protective clothing when working with large quantities.  
**Respiratory protection:** If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Solution	<b>Color:</b>	Clear, colorless
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>pH:</b>	3.5 - 4.5		

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** None known  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.  
**Hazardous Decomposition Products:** None known  
**Polymerization:** Will not occur

### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

**Acute Toxicity: (Species, Route, End Point, Dose)**

**Trimebutine maleate**

Rat Oral LD50 > 5000 mg/kg  
Mouse Oral LD50 3230 mg/kg  
Rat IP LD50 365 mg/kg

**Sodium chloride**

Rat Oral LD50 3000 mg/kg  
Mouse Oral LD 50 4000 mg/kg

**Benzyl Alcohol**

Rat Oral LD50 1.23 g/kg  
Rat Intravenous LD50 53 mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

**Irritation / Sensitization: (Study Type, Species, Severity)**

**Sodium chloride**

Eye Irritation Rabbit Moderate

## MATERIAL SAFETY DATA SHEET

Material Name: Trimebutine Maleate Injectable Solution  
Revision date: 05-Jan-2007

Page 4 of 5  
Version: 1.1

Skin Irritation Rabbit Mild

### Benzyl Alcohol

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate

Skin Irritation Guinea Pig Moderate

### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

#### Sodium chloride

10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### Trimebutine maleate

Reproductive & Fertility Rat Oral 1000 mg/kg/day NOAEL No effects at maximum dose

Reproductive & Fertility Rabbit Oral 1000 mg/kg/day NOAEL No effects at maximum dose

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

## 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

**EU Indication of danger:** Not classified

#### OSHA Label:

WARNING

May cause gastrointestinal system effects

## MATERIAL SAFETY DATA SHEET

Material Name: Trimebutine Maleate Injectable Solution  
Revision date: 05-Jan-2007

Page 5 of 5  
Version: 1.1

### Canada - WHMIS: Classifications

#### WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

#### Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-598-3

#### Water for injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

#### Trimebutine maleate

Australia (AICS):	Present
EU EINECS List	251-845-9

#### Benzyl Alcohol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-859-9

### 16. OTHER INFORMATION

#### Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

#### Prepared by:

Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet