



# MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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

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### Material Name: Ketobemidone Hydrochloride Capsules

**Trade Name:** Ketodur  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as opioid analgesic

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Microcrystalline cellulose	9004-34-6	232-674-9	*
Colloidal silicon dioxide	7631-86-9	231-545-4	*
Titanium dioxide	13463-67-7	236-675-5	*
Sucrose	57-50-1	200-334-9	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*
Ketobemidone Hydrochloride	5965-49-1	227-749-8	10 / 25 mg ***

Ingredient	CAS Number	EU EINECS List	%
Acetyltriethyl Citrate	77-89-4	201-066-5	*
Polysorbate 80	9005-65-6	Not listed	*
Gelatin	9000-70-8	232-554-6	*
Dimethyl polysiloxane	9006-65-9	Not listed	*
Eudragit RS 100	Not Assigned	Not listed	*
E172 (colorant)	Not Assigned	Not listed	*

### Additional Information:

\* Proprietary  
\*\*\* per tablet/capsule/lozenge/suppository  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Capsules  
**Signal Word:** WARNING

**Statement of Hazard:** Harmful if swallowed.  
May cause central nervous system effects

**Additional Hazard Information:**  
**Short Term:** Accidental ingestion may cause effects similar to those seen in clinical use.

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**Known Clinical Effects:** May cause effects similar to those seen in clinical use including dry mouth, blurred vision, constipation, and upset stomach. Ingestion of this material may cause effects similar to those seen in clinical use including hypotension (low blood pressure), dizziness, headache and drowsiness.

**EU Indication of danger:** Harmful

**EU Hazard Symbols:**



**EU Risk Phrases:** R22 - Harmful if swallowed.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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:** Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

**Skin Contact:** Wash skin with soap and water. If irritation occurs or persists, get medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

### 5. FIRE FIGHTING MEASURES

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

**Hazardous Combustion Products:** May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds.

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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.

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**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:** If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Avoid generating airborne dust. Wash thoroughly after handling.

**Storage Conditions:** Store as directed by product packaging.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Microcrystalline cellulose

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

### Colloidal silicon dioxide

OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO<sub>2</sub>) mg/m<sup>3</sup> TWA  
= 20 mppcf TWA  
Australia TWA = 2 mg/m<sup>3</sup> TWA

### Titanium dioxide

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

### Sucrose

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

### Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D: = 20 mppcf TWA  
ACGIH Threshold Limit Value (TWA) = 2 mg/m<sup>3</sup> TWA  
Australia TWA = 2.5 mg/m<sup>3</sup> TWA containing no asbestos fibers

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

### Ketobemidone Hydrochloride

Pfizer Occupational Exposure Band (OEB): OEB3 (control exposure to the range of >10ug/m<sup>3</sup> to < 100ug/m<sup>3</sup>)

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

### Personal Protective Equipment:

**Hands:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.

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**Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

**Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.

**Respiratory protection:** Not required for the normal use of this product. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Capsule	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 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.

### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of various forms of the active ingredient. The remaining information describes the potential hazards of the individual ingredients.

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

##### **Ketobemidone**

Rat Intravenous LD 50 10 mg/kg  
Mouse LD 50 14 mg/kg

##### **Ketobemidone Hydrochloride**

Rat Oral LD 50 215 mg/kg  
Rat Intravenous LD 50 40 mg/kg

##### **Polysorbate 80**

Rat Intravenous LD 50 1790 mg/kg  
Mouse Oral LD 50 25 g/kg

##### **Talc (non-asbestiform)**

Rat Oral LD50 > 1600 mg/kg

##### **Titanium dioxide**

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD 50 50 mg/kg

##### **Sucrose**

Rat Oral LD50 29.7 g/kg

##### **Microcrystalline cellulose**

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

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**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)

#### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

**Carcinogen Status:** See below

#### Talc (non-asbestiform)

**IARC:** Group 3

#### Colloidal silicon dioxide

**IARC:** Group 3

#### Titanium dioxide

**IARC:** Group 2B  
**OSHA:** Present

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. 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 Symbol:** Xn  
**EU Indication of danger:** Harmful

**EU Risk Phrases:**  
R22 - Harmful if swallowed.

**EU Safety Phrases:**  
S22 - Do not breathe dust.

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## OSHA Label:

WARNING

Harmful if swallowed.

May cause central nervous system effects

## 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.

### Acetyltriethyl Citrate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-066-5

### Polysorbate 80

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

### Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-674-9

### Colloidal silicon dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-545-4

### Gelatin

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-554-6

### Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5

### Sucrose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-334-9

### Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	238-877-9

### Dimethyl polysiloxane

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Australia (AICS): Present

Ketobemidone Hydrochloride  
EU EINECS List 227-749-8

Additional Information: U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule I

### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**