



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

Page 1 of 5

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

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Material Name: Ketobemidone Hydrochloride and Dimethylaminodiphenylbutylene Hydrochloride Suppositories

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
3-dimethylamino-1,1-diphenylbuten(1) hydrochloride	Not Assigned	Not listed	50 mg ***
Ketobemidone Hydrochloride	5965-49-1	227-749-8	10 mg ***

Ingredient	CAS Number	EU EINECS List	%
Macrogol 3000	Not Assigned	Not listed	*
Water, purified	7732-18-5	231-791-2	*
Macrogol 400	Not assigned	Not listed	*

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

3. HAZARDS IDENTIFICATION

Appearance: Suppository
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.
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:

MATERIAL SAFETY DATA SHEET

Material Name: Ketobemidone Hydrochloride and
Dimethylaminodiphenylbutylene Hydrochloride Suppositories
Revision date: 15-Dec-2006

Page 2 of 5

Version: 1.1



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.
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

MATERIAL SAFETY DATA SHEET

Material Name: Ketobemidone Hydrochloride and
Dimethylaminodiphenylbutylene Hydrochloride Suppositories
Revision date: 15-Dec-2006

Page 3 of 5

Version: 1.1

General Handling: 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

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/m³ to < 100ug/m³)

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.

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:

Physical State:	Suppository	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	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

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

Ketobemidone

MATERIAL SAFETY DATA SHEET

Material Name: Ketobemidone Hydrochloride and
Dimethylaminodiphenylbutylene Hydrochloride Suppositories
Revision date: 15-Dec-2006

Page 4 of 5

Version: 1.1

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

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

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.

OSHA Label:
WARNING
Harmful if swallowed.
May cause central nervous system effects

Canada - WHMIS: Classifications

MATERIAL SAFETY DATA SHEET

Material Name: Ketobemidone Hydrochloride and
Dimethylaminodiphenylbutylene Hydrochloride Suppositories
Revision date: 15-Dec-2006

Page 5 of 5

Version: 1.1

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.

Water, purified

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

Ketobemidone Hydrochloride

EU EINECS List	227-749-8
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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 13 - Disposal Considerations.

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

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End of Safety Data Sheet