MATERIAL SAFETY DATA SHEET

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

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Material Name: Ketobemidone Hydrochloride and Dimethylaminodiphenylbutylene Hydrochloride Tablets

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	25 mg ***
Magnesium stearate	557-04-0	209-150-3	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*
Ketobemidone Hydrochloride	5965-49-1	227-749-8	5 mg ***

Ingredient	CAS Number	EU EINECS List	%
Povidone	9003-39-8	Not listed	*
Lactose Monohydrate	64044-51-5	Not listed	*
Gelatin	9000-70-8	232-554-6	*
Starch	9005-25-8	232-679-6	*

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: White tablets
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:

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

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

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m^3 TWA	

Talc (non-asbestiform)

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

Starch

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA = 5 mg/m^3 TWA	total
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	
Australia TWA	= 10 mg/m^3 TWA	

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^3 to < 100ug/m^3)

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:	Tablets	**Color:**	White
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 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

Lactose Monohydrate
Rat Oral LD 50 29700 mg/kg

Povidone
Rat Oral LD50 100 g/kg

Starch
Mouse IP LD50 6600 mg/kg

Talc (non-asbestiform)
Rat Oral LD50 > 1600 mg/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

Ketobemidone Hydrochloride
Rat Oral LD 50 215 mg/kg
Rat Intravenous LD 50 40 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.

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

Povidone
IARC: Group 3

Talc (non-asbestiform)
IARC: Group 3

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

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.

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

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

EU EINECS List	209-150-3

Lactose Monohydrate

Australia (AICS):	Present

Gelatin

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

Talc (non-asbestiform)

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

Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

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 13 - Disposal Considerations.

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

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End of Safety Data Sheet