



# MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.3

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

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**Material Name: Celontin (Methsuximide) Capsules 150 and 300 mg**

**Trade Name:** Celontin®  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as anticonvulsant

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Colloidal silicon dioxide	7631-86-9	231-545-4	*
Starch	9005-25-8	232-679-6	*
Sodium lauryl sulfate	151-21-3	205-788-1	*
Methsuximide	77-41-8	201-026-7	80

Ingredient	CAS Number	EU EINECS List	%
D & C yellow No. 10	8004-92-0	Not listed	*
FD&C yellow No.6 aluminum lake	15790-07-5	239-888-1	*
Gelatin	9000-70-8	232-554-6	*

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

## 3. HAZARDS IDENTIFICATION

**Appearance:** Light yellow capsules  
**Signal Word:** WARNING

**Statement of Hazard:** May be harmful if swallowed.  
Antiepileptic drug: may cause nervous system effects.  
Possible risk of harm to the unborn child.

**Additional Hazard Information:**  
**Short Term:** Harmful if swallowed (based on animal data)  
**Long Term:** Animal studies have shown a potential to cause adverse effects on the fetus.

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**Known Clinical Effects:** The most common adverse effects seen with the therapeutic use of this drug are nausea or vomiting, constipation, weight loss, and epigastric or abdominal pain. Other less common effects include CNS depression (headache, drowsiness, dizziness, incoordination, and blurred vision), behavioral changes, hematological effects (eosinophilia, leukopenia, monocytosis, and pancytopenia with or without bone-marrow depression), and skin reactions (urticaria and Stevens-Johnson syndrome) have also been reported. Psychosis, suicidal behavior, and auditory hallucinations have been reported rarely.

**EU Indication of danger:** Harmful  
Toxic to Reproduction; Category 3

**EU Hazard Symbols:**



**EU Risk Phrases:**

R22 - Harmful if swallowed.  
R63 - Possible risk of harm to the unborn child.

**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.

### 5. FIRE FIGHTING MEASURES

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

**Hazardous Combustion Products:** No data available

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

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### 6. ACCIDENTAL RELEASE MEASURES

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

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**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.

**Storage Conditions:** Keep in tightly closed containers away from heat and light. Store in a cool, dry, well-ventilated area. Protect from light, moisture, and excessive heat (40°C).

**Storage Temperature:** Store at 25°C (77°F)

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 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

### Starch

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

### Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr: 0.3 mg/m<sup>3</sup>  
Pfizer STEL 0.75 mg/m<sup>3</sup>

### Methsuximide

Pfizer OEL TWA-8 Hr: 0.7 mg/m<sup>3</sup>  
The exposure limit(s) listed for solid components are only relevant if dust may be generated.

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

### 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 the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Capsule	Color:	Light yellow
Odor:	Odorless	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** Avoid direct sunlight, conditions that might generate heat, and sources of ignition.  
**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:** There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

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

#### **D & C yellow No. 10**

Rat Oral LD50 2000 mg/kg

#### **Sodium lauryl sulfate**

Rat Oral LD50 1288 mg/kg

#### **Starch**

Mouse IP LD50 6600 mg/kg

#### **Methsuximide**

Mouse Oral LD50 900-1405 mg/kg

Rat Oral LD50 960 mg/kg

**Inhalation Acute Toxicity** No data available

**Ingestion Acute Toxicity** See Acute toxicity table.

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

#### **Sodium lauryl sulfate**

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

**Eye Irritation / Sensitization** No data available

**Skin Irritation / Sensitization** No data available

**Subchronic Effects** The only effects seen in rodents during 28-day (mice) and 26-week (rats) studies were slight decreases in weight gain.

**Chronic Toxicity** One-year oral toxicity studies were conducted in dogs and monkeys. No signs of toxicity were seen in dogs at doses up to 80 mg/kg/day. Monkeys exhibited dose-dependent, slight to marked motor incoordination.

**Chronic Effects/Carcinogenicity** No data available

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<b>Teratogenicity</b>	Methsuximide was reported to be teratogenic in mice, causing primarily skeletal and cardiovascular defects with an incidence of 51%.
<b>Mutagenicity</b>	No data available
<b>Carcinogen Status:</b>	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below
<b>Colloidal silicon dioxide IARC:</b>	Group 3
<b>Additional Information:</b>	There have been a few cases of women treated with methsuximide during pregnancy and no adverse effects were seen in the treated women. However, in general there are reports that suggest an association between the use of anticonvulsant drugs by women with epilepsy and increased incidence of birth defects in their offspring. The data are inadequate to establish a definitive cause and effect relationship. In addition, genetic factors or the epileptic condition itself may play a greater role in causation of birth defects than the drug therapy.

### 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 Symbol:** Xn  
**EU Indication of danger:** Harmful  
Toxic to Reproduction; Category 3

**EU Risk Phrases:**  
R22 - Harmful if swallowed.  
R63 - Possible risk of harm to the unborn child.

**EU Safety Phrases:**  
S22 - Do not breathe dust.  
S36/37 - Wear suitable protective clothing and gloves.  
S53 - Avoid exposure - obtain special instructions before use.

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## OSHA Label:

WARNING

May be harmful if swallowed.

Antiepileptic drug; may cause nervous system effects.

Possible risk of harm to the unborn child.

## Canada - WHMIS: Classifications

### WHMIS hazard class:

Class D, Division 2, Subdivision A



### Colloidal silicon dioxide

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

### D & C yellow No. 10

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

### Starch

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

### FD&C yellow No.6 aluminum lake

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	239-888-1

### Gelatin

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

### Sodium lauryl sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-788-1

### Methsuximide

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	201-026-7

## 16. OTHER INFORMATION

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**Reasons for Revision:**

Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. 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**