



MATERIAL SAFETY DATA SHEET

Revision date: 26-Jul-2013

Version: 2.0

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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. HAZARDS IDENTIFICATION

Appearance: Light yellow capsules
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
Possible risk of harm to the unborn child.

Additional Hazard Information:

Short Term: Antiepileptic drug; may cause nervous system effects

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.

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:

Xn



EU Risk Phrases:

R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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2. HAZARDS IDENTIFICATION

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	*
Starch	9005-25-8	232-679-6	Not Listed	*
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	*
Methsuximide	77-41-8	201-026-7	Xn;R22 Repr.Cat.3;R63	80

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

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

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek 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.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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

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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.

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: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Sodium lauryl sulfate	
Pfizer OEL TWA-8 Hr:	0.3 mg/m ³
Starch	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Czech Republic OEL - TWA	4.0 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	4 mg/m ³
Spain OEL - TWA	10 mg/m ³
Colloidal silicon dioxide	
Australia TWA	2 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Austria OEL - MAKs	4 mg/m ³
	0.3 mg/m ³
Czech Republic OEL - TWA	0.1 mg/m ³
	4.0 mg/m ³
Estonia OEL - TWA	2 mg/m ³
Finland OEL - TWA	5 mg/m ³
Germany - TRGS 900 - TWAs	4 mg/m ³
Germany (DFG) - MAK	4 mg/m ³
Ireland OEL - TWAs	6 mg/m ³
	2.4 mg/m ³
Latvia OEL - TWA	1 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m ³
Methsuximide	
Pfizer OEL TWA-8 Hr:	0.7 mg/m ³

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
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

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

Polymerization: Will not occur .

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal conditions of use.
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers

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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

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 Moderate

Skin Irritation Rabbit Mild Moderate

Skin Sensitization - GPMT Guinea Pig Negative

Skin Sensitization - LLNA Mouse Negative

Eye Irritation / Sensitization No data available

Skin Irritation / Sensitization No data available The only effects seen in rodents during 28-day (mice) and 26-week (rats) studies were slight decreases in weight gain. 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

Teratogenicity Methsuximide was reported to be teratogenic in mice, causing primarily skeletal and cardiovascular defects with an incidence of 51%.

Sodium lauryl sulfate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Mutagenicity No data available

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Colloidal silicon dioxide

IARC:

Group 3 (Not Classifiable)

Additional Information:

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.

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12. ECOLOGICAL INFORMATION

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

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Sodium lauryl sulfate

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 3.6 mg/L

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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.

OSHA Label:
WARNING
Harmful if swallowed.
Possible risk of harm to the unborn child.

Canada - WHMIS: Classifications

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15. REGULATORY INFORMATION

WHMIS hazard class:

Class D, Division 2, Subdivision A



D & C yellow No. 10

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

Gelatin

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-554-6

Sodium lauryl sulfate

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	205-788-1

Starch

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

FD&C yellow No.6 aluminum lake

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	239-888-1

Colloidal silicon dioxide

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4

Methsuximide

California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	201-026-7

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15. REGULATORY INFORMATION

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R63 - Possible risk of harm to the unborn child.

Data Sources: Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 15 - Regulatory Information. Updated Section 3 - Composition / Information on Ingredients.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet