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

Product Identifier

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

Trade Name: CELONTIN; PETINUTIN

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as anticonvulsant

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity: Category 4
Reproductive Toxicity: Category 2

Label Elements

Signal Word: Warning

Hazard Statements: H302 - Harmful if swallowed
H361d - Suspected of damaging the unborn child

Precautionary Statements: P202 - Do not handle until all safety precautions have been read and understood
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P281 - Use personal protective equipment as required
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P330 - Rinse mouth
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
SAFETY DATA SHEET

Material Name: Celontin (Methsuximide) Capsules 150 and 300 mg
Revision date: 09-Jan-2018
Version: 3.1

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium lauryl sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
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<td>*</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
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<tr>
<td>Colloidal silicon dioxide</td>
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<td>201-026-7</td>
<td>Acute Tox.4 (H302)</td>
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<td>Repr.2 (H361d)</td>
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</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
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<tbody>
<tr>
<td>D &amp; C yellow No. 10</td>
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<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
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<td>*</td>
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<td>FD&amp;C yellow No.6 aluminum lake</td>
<td>15790-07-5</td>
<td>239-888-1</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.
SAFETY DATA SHEET

Material Name: Celontin (Methsuximide) Capsules 150 and 300 mg
Revision date: 09-Jan-2018

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

Most Important Symptoms and Effects, Both Acute and Delayed
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.

Medical Conditions Aggravated by Exposure:
None known

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician:
None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products:
Formation of toxic gases is possible during heating or fire.

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

Advice for Fire-Fighters
During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

Additional Consideration for Large Spills:
Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe 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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions:
Store as directed by product packaging.
Specific end use(s):
Pharmaceutical drug product
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Sodium lauryl sulfate
Pfizer OEL TWA-8 Hr: 0.3 mg/m³

Starch
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
5 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³

Colloidal silicon dioxide
Australia TWA 2 mg/m³
Austria OEL - MAKs 4 mg/m³
Czech Republic OEL - TWA 0.1 mg/m³
4.0 mg/m³
Estonia OEL - TWA 2 mg/m³
Finland OEL - TWA 5 mg/m³
Germany - TRGS 900 - TWAs 4 mg/m³
Germany (DFG) - MAK 4 mg/m³
Ireland OEL - TWAs 6 mg/m³
2.4 mg/m³
Latvia OEL - TWA 1 mg/m³
OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
Listed
Slovakia OEL - TWA 4.0 mg/m³
Slovenia OEL - TWA 0.3 mg/m³
Switzerland OEL -TWAs 4 mg/m³

Methsuximide
Pfizer OEL TWA-8 Hr: 700µg/m³

Exposure Controls
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.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hands: Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Water Solubility:</td>
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<tr>
<td>pH:</td>
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<td>Melting/Freezing Point (°C):</td>
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<td>Boiling Point (°C):</td>
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<tr>
<td>Gelatin</td>
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</tr>
<tr>
<td>D &amp; C yellow No. 10</td>
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<tr>
<td>Colloidal silicon dioxide</td>
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<tr>
<td>Sodium lauryl sulfate</td>
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<tr>
<td>FD&amp;C yellow No.6 aluminum lake</td>
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<tr>
<td>Starch</td>
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<tr>
<td>Methsuximide</td>
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</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
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<td>Evaporation Rate (Gram/s):</td>
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<td>Vapor Pressure (kPa):</td>
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<td>Vapor Density (g/ml):</td>
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<td>Relative Density:</td>
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<td>Viscosity:</td>
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<td>Autoignition Temperature (Solid) (°C):</td>
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<tr>
<td>Flammability (Solids):</td>
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<tr>
<td>Flash Point (Liquid) (°C):</td>
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<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Lower Explosive Limits (Liquid) (% by Vol.): No data available
Polymerization: Will not occur.

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
  Oxidizing Properties: No data available
  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
  Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
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.

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

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

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
Methsuximide
  28 Day(s) Mouse Oral 232 mg/kg/day LOAEL weight gain
11. TOXICOLOGICAL INFORMATION

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Methsuximide

Embryo / Fetal Development  Mouse  No route specified  Dose not specified  Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Sodium lauryl sulfate

Bacterial Mutagenicity (Ames)  Salmonella  Negative

Carcinogen Status:

See below

Colloidal silicon dioxide

IARC:  Group 3 (Not Classifiable)

NTP:  Reasonably Anticipated To Be A Human Carcinogen

12. ECOLOGICAL INFORMATION

Environmental Overview:

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

Toxicity:

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

Sodium lauryl sulfate

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

Persistence and Degradability:  No data available

Bio-accumulative Potential:  No data available

Mobility in Soil:  No data available

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

<table>
<thead>
<tr>
<th>Material</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>REACH - Annex IV - Exemptions from the obligations of Register:</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>D &amp; C yellow No. 10</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Schedule 6</td>
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<td>Starch</td>
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<td>232-554-6</td>
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15. REGULATORY INFORMATION

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<thead>
<tr>
<th>Substance/Preparation</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
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<tbody>
<tr>
<td>Colloidal silicon dioxide</td>
<td>Present</td>
<td>239-888-1</td>
</tr>
<tr>
<td>Methsuximide</td>
<td>Present</td>
<td></td>
</tr>
</tbody>
</table>

CERCLA/SARA 313 Emission reporting
California Proposition 65
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS): Present
EU EINECS/ELINCS List 231-545-4

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Reproductive toxicity-Cat.2; H361d - Suspected of damaging 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 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 11 - Toxicology Information. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 09-Jan-2018

Prepared by: Product Stewardship Hazard Communication

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