# SAFETY DATA SHEET

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

**Product Identifier**

<table>
<thead>
<tr>
<th>Material Name:</th>
<th>Cabergoline Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Name:</td>
<td>DOSTINEX; CABASER; SOSTILAR; CABERSIL; ACTUALENE; SOGILEN</td>
</tr>
<tr>
<td>Chemical Family:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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

**Intended Use:** Pharmaceutical product used for lactation inhibition

**Details of the Supplier of the Safety Data Sheet**

<table>
<thead>
<tr>
<th>Pfizer Inc</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Pharmaceuticals Group</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, New York 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>1-800-879-3477</td>
<td>United Kingdom</td>
</tr>
<tr>
<td></td>
<td>+00 44 (0)1304 616161</td>
</tr>
</tbody>
</table>

**Emergency telephone number (North America):** CHEMTREC (24 hours): 1-800-424-9300

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

**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Revision date:** 10-Aug-2018

**Version:** 3.1

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**2. HAZARDS IDENTIFICATION**

**Classification of the Substance or Mixture**

**GHS - Classification**

Reproductive Toxicity: Effects on or via lactation

**Label Elements**

<table>
<thead>
<tr>
<th>Signal Word:</th>
<th>Not required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Statements:</td>
<td>H362 - May cause harm to breast-fed children</td>
</tr>
<tr>
<td>Precautionary Statements:</td>
<td>P201 - Obtain special instructions before use</td>
</tr>
<tr>
<td></td>
<td>P263 - Avoid contact during pregnancy/while nursing</td>
</tr>
<tr>
<td></td>
<td>P264 - Wash hands thoroughly after handling</td>
</tr>
<tr>
<td></td>
<td>P270 - Do not eat, drink or smoke when using this product</td>
</tr>
<tr>
<td></td>
<td>P308 + P313 - IF exposed or concerned: Get medical attention/advice</td>
</tr>
</tbody>
</table>

**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 requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cabergoline</td>
<td>81409-90-7</td>
<td>Not Listed</td>
<td>Acute Tox.4 (H302) Lact.(H362)</td>
<td>1.25</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.

**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:** Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Not applicable
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
Restrict access to work area. 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. It is recommended that all operations be fully enclosed and no air recirculated. 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.

Cabergoline
Pfizer OEL TWA-8 Hr: 0.5µg/m³

Leucine
Latvia OEL - TWA 5 mg/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 disposable gloves (e.g. Nitrile, etc.) (double 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 disposable 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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

**Solvent Solubility:** No data available

**Water Solubility:** No data available

**pH:** No data available

**Melting/Freezing Point (°C):** No data available

**Boiling Point (°C):** No data available

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Cabergoline**
No data available

**Leucine**
No data available

**Lactose NF, anhydrous**
No data available

**Decomposition Temperature (°C):** No data available

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

**Flammability:**
- **Autoignition Temperature (Solid) (°C):** No data available
- **Flammability (Solids):** No data available
- **Flash Point (Liquid) (°C):** No data available
- **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
- **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

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:** None known
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
10. STABILITY AND REACTIVITY

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 active ingredient(s).

Short Term:
Active ingredient may be harmful if swallowed. (based on animal data). Accidental ingestion may cause effects similar to those seen in clinical use.

Known Clinical Effects:
Ingestion of this material may cause effects similar to those seen in clinical use including nausea, vomiting, abdominal cramps, anorexia, diarrhea, and constipation. This drug may decrease the quantity/quality of breast milk.

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

Cabergoline
- Rat Oral LD 50 383 (F) mg/kg
- Rat Para-periosteal LD 50 22mg/kg
- Mouse Oral LD 50 202 (F)mg/kg
- Mouse Intravenous LD 50 24 (F)mg/kg

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

Cabergoline
Skin Sensitization - GPMT Guinea Pig No effect

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Cabergoline
- Embryo / Fetal Development Rat Oral 0.012 mg/kg/day LOAEL Fetotoxicity
- Embryo / Fetal Development Rabbit Oral 8 mg/kg/day NOAEL Not Teratogenic
- Embryo / Fetal Development Mouse Oral 8 mg/kg/day Not Teratogenic, Maternal Toxicity

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

Cabergoline
In Vitro Mammalian Cell Mutagenicity Hamster Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
In Vitro Micronucleus Mouse Bone Marrow Negative
In Vitro Direct DNA Damage Bacteria Negative
Bacterial Mutagenicity (Ames) Salmonella Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Cabergoline
- 24 Month(s) Rat Oral 0.320 mg/kg/day Not carcinogenic
- 21 Month(s) Mouse Oral 0.980 mg/kg/day Not carcinogenic

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.

Toxicity: No data available

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, ADG or IMDG regulations.

15. REGULATORY INFORMATION

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

Cabergoline
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: Not Listed

Leucine
- CERCLA/SARA 313 Emission reporting: Not Listed
15. REGULATORY INFORMATION

California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 200-522-0

Lactose NF, anhydrous
CERCLA/SARA 313 Emission reporting Not Listed
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 200-559-2

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.
Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.
Revision date: 10-Aug-2018
Prepared by: Product Stewardship Hazard Communications

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