SAFETY DATA SHEET

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

Product Identifier

Material Name: Tussigon Tablets (Hydrocodone bitartrate and homatropine methylbromide) CII

Trade Name: TUSSIGON
Synonyms: Hydrocodone bitartrate and homatropine methylbromide tablets
Chemical Family: Opioid

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

Intended Use: Pharmaceutical product used as Narcotic antitussive analgesic

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

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>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6 Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Silicon dioxide, NF</td>
<td>7631-86-9</td>
<td>231-545-4 Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9 Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9 Not Listed</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hydrocodone bitartrate</td>
<td>34195-34-1</td>
<td>Not Listed</td>
<td>Acute Tox. 4, H302</td>
<td>3.2</td>
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<tr>
<td></td>
<td>Homatropine methylbromide</td>
<td>80-49-9</td>
<td>201-284-0 Acute Tox. 4,H302</td>
<td>1</td>
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<table>
<thead>
<tr>
<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>FD&amp;C Blue no. 1 aluminum lake</td>
<td>68921-42-6</td>
<td>272-939-6 Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>200-313-4 Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed 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.

**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.
SAFETY DATA SHEET

Material Name: Tussigon Tablets (Hydrocodone bitartrate and homatropine methylbromide) CII
Revision date: 18-Jan-2017

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. Clean up 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.

Starch, pregelatinized
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
Ireland OEL - TWAs 10 mg/m³

5 mg/m³
4 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material Name: Tussigon Tablets (Hydrocodone bitartrate and homatropine methylbromide) CII</th>
<th>Page 4 of 11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date: 18-Jan-2017</td>
<td>Version: 2.2</td>
</tr>
</tbody>
</table>

#### 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

#### Silicon dioxide, NF
- Australia TWA: 2 mg/m³
- Austria OEL - MAKs: 4 mg/m³
- Czech Republic OEL - TWA: 0.1 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
- 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

#### Talc (non-asbestiform)
- ACGIH Threshold Limit Value (TWA): 2 mg/m³
- Australia TWA: 2.5 mg/m³
- Austria OEL - MAKs: 2 mg/m³
- Belgium OEL - TWA: 2 mg/m³
- Bulgaria OEL - TWA: 1.0 fiber/cm³
- Czech Republic OEL - TWA: 2.0 mg/m³
- Denmark OEL - TWA: 0.3 fiber/cm³
- Finland OEL - TWA: 0.5 fiber/cm³
- Greece OEL - TWA: 10 mg/m³
- Hungary OEL - TWA: 2 mg/m³
- Ireland OEL - TWAs: 10 mg/m³
- Lithuania OEL - TWA: 2 mg/m³
- Netherlands OEL - TWA: 0.25 mg/m³
- OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
- Poland OEL - TWA: 4.0 mg/m³
- Portugal OEL - TWA: 2 mg/m³
- Romania OEL - TWA: 2 mg/m³
- Slovakia OEL - TWA: 2 mg/m³
- Slovenia OEL - TWA: 2 mg/m³
- Spain OEL - TWA: 2 mg/m³

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Material Name: Tussigon Tablets (Hydrocodone bitartrate and homatropine methylbromide) CII
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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

Silicon dioxide, NF

- Australia TWA: 2 mg/m³
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- 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
- Latvia OEL - TWA: 1 mg/m³
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- Listed
- Slovakia OEL - TWA: 4.0 mg/m³
- Slovenia OEL - TWA: 0.3 mg/m³
- Switzerland OEL - TWAs: 4 mg/m³

Talc (non-asbestiform)

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- Australia TWA: 2.5 mg/m³
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- Belgium OEL - TWA: 2 mg/m³
- Bulgaria OEL - TWA: 1.0 fiber/cm³
- Czech Republic OEL - TWA: 2.0 mg/m³
- Denmark OEL - TWA: 0.3 fiber/cm³
- Finland OEL - TWA: 0.5 fiber/cm³
- Greece OEL - TWA: 10 mg/m³
- Hungary OEL - TWA: 2 mg/m³
- Ireland OEL - TWAs: 10 mg/m³
- Lithuania OEL - TWA: 2 mg/m³
- Netherlands OEL - TWA: 0.25 mg/m³
- OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
- Poland OEL - TWA: 4.0 mg/m³
- Portugal OEL - TWA: 2 mg/m³
- Romania OEL - TWA: 2 mg/m³
- Slovakia OEL - TWA: 2 mg/m³
- Slovenia OEL - TWA: 2 mg/m³
- Spain OEL - TWA: 2 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

Hydrocodone bitartrate  
Pfizer Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

Homatropine methylbromide  
Pfizer Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/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.

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.)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 State:</th>
<th>Tablet</th>
<th>Color:</th>
<th>Blue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
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<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</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)

**Hydrocodone bitartrate**

- No data available

**Homatropine methylbromide**

- No data available

**Lactose NF, monohydrate**

- No data available

**Microcrystalline cellulose**

- No data available

**FD&C Blue no. 1 aluminum lake**

- No data available

**Stearic acid**

- No data available

**Silicon dioxide, NF**

- No data available

**Talc (non-asbestiform)**

- No data available

**Starch, pregelatinized**

- 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: 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: May be harmful if swallowed. (based on components).
Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, blurred vision and dilated pupils. Cases of overdosage may also lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia. Additionally, symptoms of dependence/withdrawal may occur.

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

Hydrocodone bitartrate
Rat Oral LD50 > 4640 mg/kg

Homatropine methylbromide
Rat Oral LD50 > 5000 mg/kg
Mouse Oral LD50 > 2000 mg/kg

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Stearic acid
Rat Oral LD50 > 4640 mg/kg
Rabbit Dermal LD50 > 5000 mg/kg

Talc (non-asbestiform)
Rat Oral LD50 > 1600 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.

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

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating
11. TOXICOLOGICAL INFORMATION

Stearic acid
Skin Irritation  Rabbit  Moderate
Eye Irritation  Rabbit  Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Stearic acid
30 Week(s)  Rat  Oral  300 ppm  LOAEL  Adipose tissue

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

Hydrocodone bitartrate
Reproductive & Fertility  Rat  Oral  <7 mg/kg/day  NOAEL  Maternal toxicity, Paternal toxicity
Peri-/Postnatal Development  Rat  Oral  7 mg/kg/day  NOAEL  Maternal Toxicity, Fetotoxicity

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

Stearic acid
In Vitro Bacterial Mutagenicity (Ames)  Salmonella  Negative
Unscheduled DNA Synthesis  E. coli  Negative

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

Stearic acid
26 Week(s)  Rat  Subcutaneous  0.5 mg/kg/week  NOAEL  Not carcinogenic
52 Week(s)  Mouse  Subcutaneous  0.05 mg/kg/week  LOAEL  Tumors

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

Silicon dioxide, NF
IARC:  Group 3 (Not Classifiable)
NTP:  Reasonably Anticipated To Be A Human Carcinogen

Talc (non-asbestiform)
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:  Environmental properties of the formulation have not been thoroughly 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

PZ02180
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

FD&C Blue no. 1 aluminum lake
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 272-939-6

Stearic acid
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 200-313-4

Lactose NF, monohydrate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

Starch, pregelatinized
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Ingredient</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>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon dioxide, NF</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>232-679-6</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>231-545-4</td>
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<tr>
<td>Microcrystalline cellulose</td>
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<td>232-674-9</td>
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<td>Homatropine methylbromide</td>
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<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>201-284-0</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Data Sources: Safety data sheets for individual ingredients. Publicly available toxicity information. Pfizer proprietary drug development information.
Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 18-Jan-2017

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