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

**Material Name:** Morphine Sulfate Tablets (5, 10, and 30 mg)

- Trade Name: DOLCONTIN, ALGEDOL; CONTALGIN; MORPHOLAR
- Chemical Family: Not determined
- Intended Use: Pharmaceutical active used as opioid analgesic

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

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

**Appearance:** Tablets, varying in color depending on strength

**Signal Word:** WARNING

**Statement of Hazard:** May cause harm to the unborn child. May cause harm to breastfed babies. Possible mutagen

**Additional Hazard Information:**
- **Short Term:** May be harmful if swallowed. (based on components) Dust may cause irritation if tablets are crushed or broken
- **Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.

**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.

**EU Indication of danger:** Toxic to reproduction, Category 2

**EU Hazard Symbols:**
- Mutagenic Category 3

**EU Risk Phrases:**
- R61 - May cause harm to the unborn child.
- R64 - May cause harm to breastfed babies.
- R68 - Possible risk of irreversible effects.

**Australian Hazard Classification (NOHSC):** Hazardous Substance. Non-Dangerous Goods.
MATERIAL SAFETY DATA SHEET

Material Name: Morphine Sulfate Tablets (5, 10, and 30 mg)
Revision date: 19-Oct-2007

Note:
This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine Sulfate</td>
<td>64-31-3</td>
<td>200-582-8</td>
<td>Xn;R22 Muta.Cat.3;R68 Repr.Cat.2;R61 R64</td>
<td>3-20</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9 EEC No. 456-230-0</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxyethyl cellulose</td>
<td>9004-62-0</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Purified water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose NF, anhydrous</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl cellulose</td>
<td>9004-64-2</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Film coating</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Cetearyl alcohol</td>
<td>8005-44-5</td>
<td>Not listed</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.

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: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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

Fire / Explosion Hazards: Not applicable

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). Releases to the environment should be avoided.

Storage Conditions: Store as directed by product packaging.

Storage Temperature: At or below 25°C (77°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Magnesium stearate
- ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
- Australia TWA = 10 mg/m³ TWA
- Belgium OEL - TWA = 10 mg/m³ TWA
- Ireland OEL - TWAs = 10 mg/m³ TWA except lead stearate
- Lithuania OEL - TWA = 3 mg/m³ IPRV
- Portugal OEL - TWA = 10 mg/m³ TWA does not include stearates of toxic metals
- Spain OEL - TWA = 10 mg/m³ VLA-ED not including stearates of toxic metals
- Sweden OEL - TWAs = 5 mg/m³ LLV

Titanium dioxide
- ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
- Australia TWA = 10 mg/m³ TWA
- Austria OEL - MAKs = 6 mg/m³ MAK
- Belgium OEL - TWA = 10 mg/m³ TWA
- Bulgaria OEL - TWA = 10.0 mg/m³ TWA
### MATERIAL SAFETY DATA SHEET

**Material Name:** Morphine Sulfate Tablets (5, 10, and 30 mg)  
**Revision date:** 19-Oct-2007  
**Version:** 1.0  

<table>
<thead>
<tr>
<th>Country</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Polyethylene glycol</strong></td>
<td></td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>= 1000 mg/m³ MAK</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>= 1000 mg/m³ TWA</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>= 1000 mg/m³ MAC</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>= 1000 mg/m³ TWA</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>= 1000 mg/m³ TWA</td>
</tr>
<tr>
<td><strong>Talc (non-asbestiform)</strong></td>
<td></td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>= 2 mg/m³ TWA particulate matter containing no asbestos and &lt;1% crystalline silica</td>
</tr>
<tr>
<td>ACGIH OELs - Notice of Intended Changes</td>
<td>Listed</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>= 2.5 mg/m³ TWA containing no asbestos fibers</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>= 2 mg/m³ MAK asbestos-free fibers</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>= 2 mg/m³ TWA</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>= 1.0 fiber/cm³ TWA containing &lt;2% uncombined crystalline silicon dioxide</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>= 3.0 mg/m³ TWA</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>= 6.0 mg/m³ TWA</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>= 2.0 mg/m³ TWA</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>= 0.3 fiber/cm³ TWA</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>= 0.5 mg/m³ TWA</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>= 1 mg/m³ TWA</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>= 10 mg/m³ TWA</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>= 10 mg/m³ TWA</td>
</tr>
<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
<td>= 20 mppcf TWA</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>= 1.0 mg/m³ NDS</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>= 4.0 mg/m³ NDS</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>= 2 mg/m³ TWA</td>
</tr>
</tbody>
</table>
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.

**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:**

- **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 airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Tablet</td>
</tr>
<tr>
<td>Color</td>
<td>Various According to product specification</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

### 10. STABILITY AND REACTIVITY

- **Stability:** Stable under normal conditions of use.
- **Conditions to Avoid:** None known
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

### 11. TOXICOLOGICAL INFORMATION

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

**Acute Toxicity:** (Species, Route, End Point, Dose)
Magnesium stearate
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³

Titanium dioxide
- Rat Oral LD50 > 7500 mg/kg
- Rat Subcutaneous LD 50 50 mg/kg

Talc (non-asbestiform)
- Rat Oral LD50 > 1600 mg/kg

Morphine Sulfate
- Rat Oral LD50 461 mg/kg
- Rat Intravenous LD50 70 mg/kg
- Rat Intraperitoneal LD50 235 mg/kg
- Mouse Oral LD50 600 mg/kg
- Mouse Intravenous LD50 156 mg/kg

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

Polyethylene glycol
- Eye Irritation Rabbit Mild
- Skin Irritation Rabbit Mild

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

Morphine Sulfate
- 18 Week(s) Rat Oral 60 g/kg LOAEL Lungs
- 15 Day(s) Rat Subcutaneous 3144 mg/kg LOAEL Kidney, Ureter, Bladder
- 9 Week(s) Rat Subcutaneous 3150 mg/kg LOAEL

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

Morphine Sulfate
- Embryo / Fetal Development Mouse Subcutaneous 0.15 mg/kg LOAEL Teratogenic
- Embryo / Fetal Development Hamster Subcutaneous 35 mg/kg LOAEL Teratogenic
- Embryo / Fetal Development Mouse Oral 200 mg/kg LOAEL Teratogenic
- Embryo / Fetal Development Rat Subcutaneous 35 mg/kg LOAEL Fetotoxicity

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

Morphine Sulfate
- In Vivo Micronucleus Mouse Positive
- In Vivo Chromosome Aberration Mouse Lymphocytes Positive
- In Vitro Direct DNA Damage Human Lymphocytes Positive
- In Vitro Chromosome Aberration Mouse Negative
- Dominant Lethal Assay Drosophila Negative

Carcinogen Status: See below

Titanium dioxide
- IARC: Group 2B
- OSHA: Present
12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Toxic to reproduction, Category 2
Mutagenic Category 3

EU Risk Phrases:
R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.
R68 - Possible risk of irreversible effects.

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
May cause harm to the unborn child.
May cause harm to breastfed babies.
Possible mutagen
Canada - WHMIS: Classifications

WHMIS hazard class:
D1b  toxic materials
D2a  very toxic materials

Morphine Sulfate
Australia (AICS): Present
EU EINECS/ELINCS List 200-582-8

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

Purified water
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register:
EU EINECS/ELINCS List 231-791-2

Magnesium stearate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 209-150-3

Lactose NF, anhydrous
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 200-559-2

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

Titanium dioxide
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 236-675-5

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

Talc (non-asbestiform)
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 238-877-9
EEC No. 456-230-0
Additional Information: U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule II

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.
R68 - Possible risks of irreversible effects.

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

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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