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

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): 1-800-262-8200
Emergency telephone number: ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Tramadol Hydrochloride Soluble Tablets

Trade Name: Not determined
Chemical Family: Not determined
Intended Use: analgesic

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tramadol Hydrochloride</td>
<td>73806-49-2</td>
<td>Not listed</td>
<td>50 mg ***</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
<tr>
<td>Maize starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>*</td>
</tr>
<tr>
<td>Flavoring agents</td>
<td>Not assigned</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium saccharin</td>
<td>128-44-9</td>
<td>204-886-1</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Tablets
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
May cause central nervous system effects
Eye Contact: Active ingredient is not an irritant (based on animal data)
Skin Contact: Active ingredient is not a skin irritant (based on animal data)
Inhalation: An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).
Ingestion: Harmful if swallowed (based on animal data).
MATERIAL SAFETY DATA SHEET

Material Name: Tramadol Hydrochloride Soluble Tablets
Revision date: 27-Oct-2006
Page 2 of 7
Version: 1.2

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, and dilated pupils. Cases of severe overdose may lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.

Potential Health Effects: Use of this drug is habit forming. Addiction may occur.

EU Indication of danger: Harmful

EU Risk Phrases: R22 - Harmful if swallowed.

Additional Information: For a more detailed discussion of potential health hazards and toxicity see Section 11. 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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get 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.

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.

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: Wipe up with a damp cloth and place in container for disposal. 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: Contain the source of the spill or leak if it is safe to do so. Vacuum or sweep material into appropriate container for disposal.

7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. Use with adequate ventilation.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Microcrystalline cellulose

<table>
<thead>
<tr>
<th>OSHA - Final PELs - TWAs:</th>
<th>= 15 mg/m³ TWA total</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>= 5 mg/m³ TWA</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>= 10 mg/m³ TWA</td>
</tr>
</tbody>
</table>

Magnesium stearate

| ACGIH Threshold Limit Value (TWA) | = 10 mg/m³ TWA except stearates of toxic metals |
| Australia TWA | = 10 mg/m³ TWA |

Colloidal silicon dioxide

<table>
<thead>
<tr>
<th>OSHA - Final PELs - Table Z-3 Mineral D:</th>
<th>(80)/(% SiO2) mg/m³ TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>= 20 mppcf TWA</td>
</tr>
<tr>
<td>= 2 mg/m³ TWA</td>
<td></td>
</tr>
</tbody>
</table>

Maize starch

<table>
<thead>
<tr>
<th>OSHA - Final PELs - TWAs:</th>
<th>= 15 mg/m³ TWA total</th>
</tr>
</thead>
<tbody>
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<td>ACGIH Threshold Limit Value (TWA)</td>
<td>= 5 mg/m³ TWA</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>= 10 mg/m³ TWA</td>
</tr>
</tbody>
</table>

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system. For laboratory use, handle in a lab fume hood.

Personal Protective Equipment:

| Hands | Wear impervious gloves if skin contact is possible. |
| Eyes  | Safety glasses or goggles |
| Skin  | Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. |
| Respiratory protection | Respiratory protection is recommended as a precaution to minimize exposure when handling this material in bulk. |

9. PHYSICAL AND CHEMICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color</td>
<td>No data available.</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: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

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)

Tramadol Hydrochloride
- Rat Oral LD50 228 mg/kg
- Rat Intravenous LD50 57.6 mg/kg
- Rat Subcutaneous LD50 286 mg/kg
- Mouse Oral LD50 270 mg/kg
- Mouse Intravenous LD50 60.4 mg/kg

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

Magnesium stearate
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³

Sodium saccharin
- Mouse Oral LD50 17.5 g/kg
- Rat Oral LD50 14.2 - 17 g/kg
- Rat Intraperitoneal LD50 7100 mg/kg

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

Microcrystalline cellulose
- Skin Irritation Rabbit Non-irritating
- Eye Irritation Rabbit Non-irritating

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

Tramadol Hydrochloride
- 6 Week(s) Rat Oral 20 mg/kg/day NOAEL
- 26 Week(s) Dog Oral 10 mg/kg/day NOAEL

Sodium saccharin
- 36 Week(s) Rat Oral 756 g/kg LOAEL Kidney, Ureter, Bladder
- 54 Day(s) Rat Oral 32400 mg/kg LOAEL Immune system

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

Tramadol Hydrochloride
- Reproductive & Fertility Rat Oral 50-75 mg/kg NOAEL Fertility
- Embryo / Fetal Development Rat Oral 25 mg/kg LOAEL Maternal Toxicity, Fetotoxicity
Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Tramadol Hydrochloride
Bacterial Mutagenicity (Ames)  Salmonella ,  E. coli   Negative
In Vivo Chromosome Aberration Chinese Hamster Ovary (CHO) cells  Negative
In Vivo Micronucleus Mouse Bone Marrow  Negative
In Vitro Micronucleus  Rat  Positive
In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma  Positive

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

Tramadol Hydrochloride
2 Year(s)  Mouse  Oral  30 mg/kg/day  LOAEL  Liver, Lungs, Tumors
2 Year(s)  Rat  Oral  30 mg/kg/day  NOAEL  Not carcinogenic

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

Sodium saccharin
IARC:  Group 3

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures:  Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol:  Xn
EU Indication of danger: Harmful

EU Risk Phrases:
R22 - Harmful if swallowed.

EU Safety Phrases:
S22 - Do not breathe dust.

OSHA Label:
WARNING
Harmful if swallowed.
May cause central nervous system effects

Canada - WHMIS: Classifications

WHMIS hazard class:
D1b toxic materials

Microcrystalline cellulose
  Inventory - United States TSCA - Sect. 8(b)  XU
  Australia (AICS):  Present
  EU EINECS List  232-674-9

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

Colloidal silicon dioxide
  Inventory - United States TSCA - Sect. 8(b)  Present
  Australia (AICS):  Present
  EU EINECS List  231-545-4

Maize starch
  Inventory - United States TSCA - Sect. 8(b)  XU
  Australia (AICS):  Present
  EU EINECS List  232-679-6

Sodium saccharin
  Inventory - United States TSCA - Sect. 8(b)  Present
  Australia (AICS):  Present
  EU EINECS List  204-886-1

16. OTHER 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.

End of Safety Data Sheet