



# MATERIAL SAFETY DATA SHEET

Revision date: 27-Oct-2006

Version: 1.2

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

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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

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

Ingredient	CAS Number	EU EINECS List	%
Colloidal silicon dioxide	7631-86-9	231-545-4	*
Flavoring agents	Not assigned	Not listed	*
Sodium saccharin	128-44-9	204-886-1	*

### 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).

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**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.

**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.

### 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.

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**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

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

### Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA except stearates of toxic metals  
Australia TWA = 10 mg/m<sup>3</sup> TWA

### Colloidal silicon dioxide

OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO<sub>2</sub>) mg/m<sup>3</sup> TWA  
= 20 mppcf TWA  
Australia TWA = 2 mg/m<sup>3</sup> TWA

### Maize starch

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

**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:

**Physical State:** Tablets **Color:** No data available.  
**Molecular Formula:** Mixture **Molecular Weight:** Mixture

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### 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/m<sup>3</sup>

##### **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

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Embryo / Fetal Development	Rabbit	Oral	75 mg/kg	LOAEL	Maternal Toxicity, Fetotoxicity
Embryo / Fetal Development	Mouse	Oral	120 mg/kg	LOAEL	Maternal Toxicity, Fetotoxicity
Peri-/Postnatal Development	Rat	Oral	50 mg/kg	LOAEL	Maternal Toxicity, Fetotoxicity

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

#### Tramadol Hydrochloride

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vivo</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vivo</i> Micronucleus	Mouse Bone Marrow	Negative
<i>In Vitro</i> Micronucleus	Rat	Positive
<i>In Vitro</i> 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

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**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



<b>Microcrystalline cellulose</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-674-9
<b>Magnesium stearate</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3
<b>Colloidal silicon dioxide</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-545-4
<b>Maize starch</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6
<b>Sodium saccharin</b>	
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

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**End of Safety Data Sheet**