



MATERIAL SAFETY DATA SHEET

Revision date: 31-Jan-2007

Version: 1.2

Page 1 of 5

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): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Tramadol Hydrochloride Solution for Injection

Trade Name:	Nobligan; Tramal
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as analgesic

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Tramadol Hydrochloride	73806-49-2	Not listed	5

Ingredient	CAS Number	EU EINECS List	%
Water for injection	7732-18-5	231-791-2	*
Sodium acetate	127-09-3	204-823-8	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Solution
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
May cause central nervous system effects

Additional Hazard Information:
Short Term: Not an eye irritant ; Active ingredient is not a skin irritant ; Harmful if swallowed (based on animal data) .

Long Term: Use of this drug is habit forming. Addiction may occur.
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.

EU Indication of danger: Not classified

MATERIAL SAFETY DATA SHEET

Material Name: Tramadol Hydrochloride Solution for Injection
Revision date: 31-Jan-2007

Page 2 of 5
Version: 1.2

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: 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 spill with absorbent material. 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

MATERIAL SAFETY DATA SHEET

Material Name: Tramadol Hydrochloride Solution for Injection
Revision date: 31-Jan-2007

Page 3 of 5
Version: 1.2

General Handling: Avoid contact with skin and clothing. Use with adequate ventilation. Wash thoroughly after handling.

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. Respiratory protection is recommended as a precaution to minimize exposure when handling this material in bulk.

9. PHYSICAL AND CHEMICAL PROPERTIES:

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

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: There are no data for this formulation. The information included in this section describes the potential hazards of the active ingredient.

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

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

Tramadol Hydrochloride

6 Week(s)	Rat	Oral	20 mg/kg/day	NOAEL
-----------	-----	------	--------------	-------

MATERIAL SAFETY DATA SHEET

Material Name: Tramadol Hydrochloride Solution for Injection
Revision date: 31-Jan-2007

Page 4 of 5
Version: 1.2

26 Week(s) Dog Oral 10 mg/kg/day NOEL

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

Tramadol Hydrochloride

Reproductive & Fertility	Rat	Oral	50-75 mg/kg	NOEL	Fertility
Embryo / Fetal Development	Rat	Oral	25 mg/kg	LOEL	Maternal Toxicity, Fetotoxicity
Embryo / Fetal Development	Rabbit	Oral	75 mg/kg	LOEL	Maternal Toxicity, Fetotoxicity
Embryo / Fetal Development	Mouse	Oral	120 mg/kg	LOEL	Maternal Toxicity, Fetotoxicity
Peri-/Postnatal Development	Rat	Oral	50 mg/kg	LOEL	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	LOEL	Liver, Lungs, Tumors
2 Year(s)	Rat	Oral	30 mg/kg/day	NOEL	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 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.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

MATERIAL SAFETY DATA SHEET

Material Name: Tramadol Hydrochloride Solution for Injection
Revision date: 31-Jan-2007

Page 5 of 5
Version: 1.2

OSHA Label:

WARNING

Harmful if swallowed.

May cause central nervous system effects

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 1, Subdivision B



Water for injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

Sodium acetate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-823-8

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.
Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage.
Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability
and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal
Considerations. Updated Section 15 - Regulatory 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