



MATERIAL SAFETY DATA SHEET

Revision date: 31-Jan-2007

Version: 1.4

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

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CHEMTREC (24 hours): 1-800-424-9300

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

Material Name: Tramadol Hydrochloride Solution/Oral Drops

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	10
Glycerol	56-81-5	200-289-5	*
Sucrose	57-50-1	200-334-9	*
Propylene glycol	57-55-6	200-338-0	*

Ingredient	CAS Number	EU EINECS List	%
Sodium saccharin	128-44-9	204-886-1	*
Sodium cyclamate	139-05-9	205-348-9	*
Purified water	7732-18-5	231-791-2	*
Potassium sorbate	590-00-1	Not listed	*
Flavoring agents	Not assigned	Not listed	*
Castor oil	8001-79-4	232-293-8	*

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.

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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.

EU Indication of danger: Not classified

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: 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.

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7. HANDLING AND STORAGE

General Handling: Avoid contact with eyes, 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

Glycerol

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Sucrose

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Propylene glycol

Australia TWA = 10 mg/m³ TWA
= 150 ppm TWA
= 474 mg/m³ TWA

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. 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.

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: Fine particles (such as dust and mists) may fuel fires/explosions.

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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

Glycerol

Rat Oral LD 50 12600 mg/kg

Sodium saccharin

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

Sodium cyclamate

Rat Oral LD50 1280 mg/kg

Sucrose

Rat Oral LD50 29.7 g/kg

Potassium sorbate

Mouse Oral LD50 3800 mg/kg
Rat Oral LD50 4340 mg/kg

Propylene glycol

Mouse Oral LD50 22,000 mg/kg
Rat Oral LD50 20,000 mg/kg
Rabbit Dermal LD50 20,800 mg/kg

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

Glycerol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

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

Glycerol

28 Day(s) Rat Oral 16800 mg/kg LOAEL Endocrine system

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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
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

Glycerol

Reproductive & Fertility-Males Rat Oral 100 mg/kg LOEL Fertility

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

Sodium saccharin

IARC: Group 3

Sodium cyclamate

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: Dispose of waste in accordance with all applicable laws and regulations.

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14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

WARNING

Harmful if swallowed.

May cause central nervous system effects

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 1, Subdivision B



Glycerol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-289-5

Sodium saccharin

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

Sodium cyclamate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-348-9

Sucrose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-334-9

Purified water

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

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Potassium sorbate

Inventory - United States TSCA - Sect. 8(b) Present

Propylene glycol

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 200-338-0

Castor oil

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 232-293-8

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet