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

Product Identifier

Material Name: Tramadol Hydrochloride Solution/Oral Drops
Trade Name: Nobligan; Tramal
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as analgesic

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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:
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

EU Classification:
EU Indication of danger: Not classified

Label Elements

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards
Australian Hazard Classification (NOHSC):

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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

Hazardous
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
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<tr>
<td>Tramadol Hydrochloride</td>
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Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES

**Description of 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.

**Most Important Symptoms and Effects, Both Acute and Delayed**

**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.

**Medical Conditions Aggravated by Exposure:** None known

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:** None

5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
SAFETY DATA SHEET

Material Name: Tramadol Hydrochloride Solution/Oral Drops
Revision date: 04-Apr-2015
Page 3 of 11
Version: 1.5

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

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Sucrose
- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- Australia TWA 10 mg/m³
- Belgium OEL - TWA 10 mg/m³
- Bulgaria OEL - TWA 10.0 mg/m³
- Estonia OEL - TWA 10 mg/m³
- France OEL - TWA 10 mg/m³
- Ireland OEL - TWAs 10 mg/m³
- Latvia OEL - TWA 5 mg/m³
- Lithuania OEL - TWA 10 mg/m³
- OSHA - Final PELS - TWAs: 15 mg/m³
- Portugal OEL - TWA 10 mg/m³
- Slovakia OEL - TWA 6 mg/m³
- Spain OEL - TWA 10 mg/m³

Glycerol
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
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<tr>
<th>Country</th>
<th>OEL - TWA</th>
<th>OEL - MAK</th>
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<td>Czech Republic OEL - TWA</td>
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Propylene glycol

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<td>10 mg/m³</td>
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<td>470 mg/m³</td>
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<td>10 mg/m³</td>
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<td>Latvia OEL - TWA</td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>7 mg/m³</td>
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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.

Tramadol Hydrochloride

Pfizer Occupational Exposure Band (OEB):

OEB 2 (control exposure to the range of 100μg/m³ to < 1000μg/m³)

Exposure Controls

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 air contamination levels below the exposure limits or within the OEB range listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Not required for the normal use of this product. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

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. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: Not required for the normal use of this product. Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solution
Odor: No data available.
Molecular Formula: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)

Deammoniation Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
  Autoignition Temperature (Solid) (°C): No data available
  Flammability (Solids): No data available
  Flash Point (Liquid) (°C): No data available
  Upper Explosive Limits (Liquid) (% by Vol.): No data available
  Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
  Oxidizing Properties: No data available
  Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
10. STABILITY AND REACTIVITY

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.
Hazardous Decomposition Products: No data available.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

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.

Acute Toxicity: (Species, Route, End Point, Dose)

**Tramadol Hydrochloride**
- Rat Oral LD50 228 mg/kg
- Rat Para-periosteal 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 LD50 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**
- Rat Oral LD50 22,000 mg/kg
- Mouse Oral LD50 24,900 mg/kg
- Rabbit Dermal LD50 20,800 mg/kg

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

**Glycerol**
11. TOXICOLOGICAL INFORMATION

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

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

Sucrose
Bacterial Mutagenicity (Ames)  Salmonella  Negative

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

Tramadol Hydrochloride
2 Year(s)  Mouse  Oral  30 mg/kg/day  NOEL  Not carcinogenic
2 Year(s)  Rat  Oral  30 mg/kg/day  NOAEL  Not carcinogenic
11. TOXICOLOGICAL INFORMATION

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 (Not Classifiable)

Sodium cyclamate
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Partition Coefficient: (Method, pH, Endpoint, Value)
Tramadol Hydrochloride
Predicted 7 Log P 1.34

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture
## 15. REGULATORY INFORMATION

### Canada - WHMIS: Classifications

**WHMIS hazard class:**
- Non-controlled

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

### Tramadol Hydrochloride

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<thead>
<tr>
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<tr>
<td>California Proposition 65</td>
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<td>EU EINECS/ELINCS List</td>
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### Sodium cyclamate

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<td>Inventory - United States TSCA - Sect. 8(b)</td>
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### Purified water

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### Sodium saccharin

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15. REGULATORY INFORMATION

Glycerol

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<td>Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern 200-289-5</td>
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Potassium sorbate

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Propylene glycol

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Flavoring agents

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Castor oil

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16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed

Xn - Harmful

R22 - Harmful if swallowed.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.
SAFETY DATA SHEET

Material Name: Tramadol Hydrochloride Solution/Oral Drops
Revision date: 04-Apr-2015

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Revision date: 04-Apr-2015
Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet