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

Product Identifier

Material Name: Tramadol Hydrochloride Modified Release Tablets
Trade Name: Nobligan Retard
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
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification
Acute Oral Toxicity: Category 4

EU Classification:
EU Indication of danger: Harmful
EU Risk Phrases:
R22 - Harmful if swallowed.

Label Elements
Signal Word: Warning
Hazard Statements: H302 - Harmful if swallowed

Precautionary Statements:
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P301+ P330 + P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting
P501 - Dispose of contents/container in accordance with all local and national regulations
SAFETY DATA SHEET

Material Name: Tramadol Hydrochloride Modified Release Tablets

Revision date: 04-Apr-2015

Version: 1.3

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

<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>
</tr>
</thead>
<tbody>
<tr>
<td>Tramadol Hydrochloride</td>
<td>73806-49-2</td>
<td>Not Listed</td>
<td>Xn; R22</td>
<td>Acute Tox.3 (H301)</td>
<td>100-200 mg***</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Macrogol 6000</td>
<td>Not assigned</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Red iron oxide</td>
<td>Not assigned</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Brown iron oxide</td>
<td>Not assigned</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Quinoline yellow lake (E104)</td>
<td>Not assigned</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</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. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

PZ00235
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: Wash skin with soap and water. 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: Formation of toxic gases is possible during heating or fire.

Products: Not applicable

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

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

| Material Name | Control Parameters | ACGIH Threshold Limit Value (TWA) | Australia TWA | Belgium OEL - TWA | Estonia OEL - TWA | France OEL - TWA | Ireland OEL - TWAs | Latvia OEL - TWA | Lithuania OEL - TWA | Sweden OEL - TWAs | Portugal OEL - TWA | Romania OEL - TWA | Russia OEL - TWA | Spain OEL - TWA | Switzerland OEL - TWAs | Vietnam OEL - TWAs |
|---------------|--------------------|----------------------------------|--------------|------------------|-----------------|----------------|-------------------|----------------|-------------------|-----------------|-----------------|----------------|-----------------|----------------|-----------------|-------------------|----------------|
| Microcrystalline cellulose |            | 10 mg/m³                         | 10 mg/m³     | 10 mg/m³         | 10 mg/m³        | 10 mg/m³       | 10 mg/m³          | 2 mg/m³         | 5 mg/m³           | 5 mg/m³         | 10 mg/m³        | 10 mg/m³        | 6 mg/m³         | 10 mg/m³         | 3 mg/m³           | 10 mg/m³         |
| Magnesium stearate |            | 10 mg/m³                          |              |                  |                 |                |                   |                 |                   |                 |                 |                 |                 |                 |                   |                   |
| Colloidal silicon dioxide |            | 2 mg/m³                          | 4 mg/m³       | 0.3 mg/m³        | 0.1 mg/m³       | 4.0 mg/m³      |                   |                 |                   |                 | 2 mg/m³         | 5 mg/m³         | 6 mg/m³         |                   | 2.4 mg/m³        |                   |
| Propylene glycol |            | 150 ppm                           | 474 mg/m³     | 10 mg/m³         |                  |                |                   |                 |                   |                 |                 |                 |                 |                 |                   |                   |
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWAs</th>
<th>ACGIH Threshold Limit Value (TWA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ireland</td>
<td>150 ppm</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>470 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Latvia</td>
<td>7 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Lithuania</td>
<td>7 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Poland</td>
<td>10.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Portugal</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Romania</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Russia</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td>6 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Vietnam</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Belgium</td>
<td>1.0 fiber/cm³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Belgium OEL</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Bulgaria</td>
<td>1.0 fiber/cm³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Denmark</td>
<td>10.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Estonia</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>France</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Greece</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Greece OEL</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Latvia OEL</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>France OEL</td>
<td>10 mg/m³</td>
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</tr>
<tr>
<td>Greece OEL</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland OEL</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Latvia OEL</td>
<td>4 mg/m³</td>
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</tr>
<tr>
<td>Lithuania OEL</td>
<td>5 mg/m³</td>
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</tr>
<tr>
<td>OSHA - Final PELs</td>
<td>15 mg/m³</td>
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</tr>
<tr>
<td>Poland OEL</td>
<td>10.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Portugal OEL</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Romania OEL</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Russia OEL</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Spain OEL</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Sweden OEL</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL</td>
<td>3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Vietnam OEL</td>
<td>6 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACNIH Threshold Limit Value (TWA)</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>2.5 mg/m³</td>
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</tr>
<tr>
<td>Austria OEL</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Belgium</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Bulgaria OEL</td>
<td>1.0 fiber/cm³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Czech Republic OEL</td>
<td>2.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Denmark OEL</td>
<td>0.3 fiber/cm³</td>
<td></td>
</tr>
<tr>
<td>Finland OEL</td>
<td>0.5 fiber/cm³</td>
<td></td>
</tr>
<tr>
<td>Greece OEL</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Hungary OEL</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland OEL</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL</td>
<td>0.8 mg/m³</td>
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</tr>
<tr>
<td>Netherlands OEL</td>
<td>0.25 mg/m³</td>
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</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Substance</th>
<th>OEB 2 (control exposure to the range of 100ug/m³ to &lt; 1000ug/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
<td>20 mppcf</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1.0 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
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<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
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<tr>
<td>Spain OEL - TWA</td>
<td>2 mg/m³</td>
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<tr>
<td>Sweden OEL - TWAs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

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):

- 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Tablets</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available</td>
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<tr>
<td>Water Solubility</td>
<td>No data available</td>
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<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>No data available</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Hydroxypropyl methylcellulose
No data available

Microcrystalline cellulose
No data available

Magnesium stearate
No data available

Lactose NF, monohydrate
No data available

Macrogol 6000
No data available

Talc (non-asbestiform)
No data available

Titanium dioxide
No data available

Tramadol Hydrochloride
Predicted Log P 1.34

Propylene glycol
No data available

Colloidal silicon dioxide
No data available

Red iron oxide
No data available

Brown iron oxide
No data available

Quinoline yellow lake (E104)
No data available

Decomposition 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: None known

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition: No data available

Products:

PZ00235
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:
Active ingredient is not a skin irritant; Not an eye 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)

Hydroxypropyl methylcellulose
Rat Oral LD50 > 10,000 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

Talc (non-asbestiform)
Rat Oral LD50 > 1600 mg/kg

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD50 50 mg/kg

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

Propylene glycol
Rat Oral LD50 22,000 mg/kg
Mouse Oral LD50 24,900mg/kg
Rabbit Dermal LD50 20,800mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating
11. TOXICOLOGICAL INFORMATION

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

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

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  NOEL  Not carcinogenic
2 Year(s)  Rat  Oral  30 mg/kg/day  NOAEL  Not carcinogenic

Carcinogen Status:  See below

Talc (non-asbestiform)
IARC:  Group 3 (Not Classifiable)

Titanium dioxide
IARC:  Group 2B (Possibly Carcinogenic to Humans)

Colloidal silicon dioxide
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: 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

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 1, Subdivision B
15. REGULATORY INFORMATION

Tramadol Hydrochloride

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Hydroxypropyl methylcellulose

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: Not Listed

Microcrystalline cellulose

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex XVII - Restrictions on Certain Dangerous Substances: Use restricted. See item 9[f]. powder
- EU EINECS/ELINCS List: 232-674-9

Magnesium stearate

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 209-150-3

Colloidal silicon dioxide

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 231-545-4

Lactose NF, monohydrate

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: Not Listed

Macrogol 6000

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed
15. REGULATORY INFORMATION

Propylene glycol
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 200-338-0

Titanium dioxide
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 236-675-5

Red iron oxide
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Brown iron oxide
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Quinoline yellow lake (E104)
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Talc (non-asbestiform)
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 238-877-9

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.
Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

Revision date: 04-Apr-2015
Prepared by: Product Stewardship Hazard Communication

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End of Safety Data Sheet