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

Product Identifier

Material Name: Tramadol Hydrochloride Soluble Tablets

Trade Name: Nobligan

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: Xn - 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
P330 - Rinse mouth
P501 - Dispose of contents/container in accordance with all local and national regulations

PZ00228
Other Hazards
Australian Hazard Classification (NOHSC):

No data available

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>
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</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>
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<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
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<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Maize starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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</tbody>
</table>

<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>Flavering agents</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium saccharin</td>
<td>128-44-9</td>
<td>204-886-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
*** per tablet/capsule/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

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 Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: 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). Wash thoroughly after handling. 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
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

**Microcrystalline cellulose**

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Component</th>
<th>TWA</th>
<th>ACGIH Threshold Limit Value (TWA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ACGIH</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Australia TWA</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
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<tr>
<td></td>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
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<tr>
<td></td>
<td>France OEL - TWA</td>
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<tr>
<td></td>
<td>Ireland OEL - TWA</td>
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<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Latvia OEL - TWA</td>
<td>2 mg/m³</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>OSHA - Final PELs - TWAs</td>
<td>15 mg/m³</td>
<td>15 mg/m³</td>
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<tr>
<td></td>
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<td>10 mg/m³</td>
</tr>
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<tr>
<td></td>
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<tr>
<td></td>
<td>Switzerland OEL - TWAs</td>
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<td>Vietnam OEL - TWAs</td>
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**Magnesium stearate**

<table>
<thead>
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<th>TWA</th>
<th>ACGIH Threshold Limit Value (TWA)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>ACGIH</td>
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<tr>
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<tr>
<td></td>
<td>Sweden OEL - TWAs</td>
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**Colloidal silicon dioxide**

<table>
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<tr>
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<td>Austria OEL - MAKs</td>
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<tr>
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<td></td>
<td>Estonia OEL - TWA</td>
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<td></td>
<td>Finland OEL - TWA</td>
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<td>5 mg/m³</td>
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<tr>
<td></td>
<td>Germany - TRGS 900 - TWAs</td>
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<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
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<td>4.0 mg/m³</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>0.3 mg/m³</td>
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**Maize starch**

<table>
<thead>
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<th>Component</th>
<th>TWA</th>
<th>ACGIH Threshold Limit Value (TWA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ACGIH</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Australia TWA</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Belgium OEL - TWA</td>
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<td>10.0 mg/m³</td>
<td>10.0 mg/m³</td>
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<tr>
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<td>Czech Republic OEL - TWA</td>
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<td>4.0 mg/m³</td>
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<td></td>
<td>Greece OEL - TWA</td>
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<td></td>
<td></td>
<td>5 mg/m³</td>
<td>5 mg/m³</td>
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</tbody>
</table>
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWAs 10 mg/m³</th>
<th>OEL - TWAs 4 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>4 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>3 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

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:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
- **Eyes:** Wear safety glasses or goggles if eye contact is possible.
- **Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
- **Respiratory protection:** 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>
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<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>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
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<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>Predicted 7 Log P 1.34</td>
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<tr>
<td>Tramadol Hydrochloride</td>
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</tr>
<tr>
<td>Odor Threshold</td>
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</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

**Material Name:** Tramadol Hydrochloride Soluble Tablets

**Molecular Formula:** Mixture

**Color:** No data available

**Odor Threshold:** No data available

**Molecular Weight:** 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:** Predicted 7 Log P 1.34

**Tramadol Hydrochloride**

**Microcrystalline cellulose** No data available

**Magnesium stearate** No data available

**Flavoring agents** No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

Maize starch
No data available

Sodium saccharin
No data available

Colloidal silicon dioxide
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

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: Not an eye irritant. Not a skin irritant (based on components).

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>228 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Para-periosteal</td>
<td>LD50</td>
<td>57.6 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Subcutaneous</td>
<td>LD50</td>
<td>286 mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>270 mg/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Intravenous</td>
<td>LD50</td>
<td>60.4 mg/kg</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

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

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

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

Tramadol Hydrochloride
6 Week(s) Rat Oral 20 mg/kg/day NOAEL
28 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
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))
11. TOXICOLOGICAL INFORMATION

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: 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)

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

<table>
<thead>
<tr>
<th>Material Name</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>EU EINECS/ELINCS List</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>REACH - Annex XVII - Restrictions on Certain Dangerous Substances:</th>
<th>EU EINECS/ELINCS List</th>
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<tbody>
<tr>
<td><strong>Tramadol Hydrochloride</strong></td>
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<td>Not Listed</td>
<td></td>
<td></td>
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<td>Use restricted. See item 9[f]. powder</td>
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<tr>
<td><strong>Microcrystalline cellulose</strong></td>
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<td>Not Listed</td>
<td>Present</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Magnesium stearate</strong></td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>209-150-3</td>
</tr>
<tr>
<td><strong>Colloidal silicon dioxide</strong></td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td></td>
<td></td>
<td></td>
<td>231-545-4</td>
</tr>
<tr>
<td><strong>Flavoring agents</strong></td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Maize starch</strong></td>
<td>Not Listed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: WHMIS hazard class: Class D, Division 1, Subdivision B*
15. REGULATORY INFORMATION

California Proposition 65  Not Listed
Inventory - United States TSCA - Sect. 8(b)  Present
Australia (AICS):  Present
REACH - Annex IV - Exemptions from the obligations of Register:
EU EINECS/ELINCS List  232-679-6

Sodium saccharin
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  204-886-1

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:  The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

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. Added Pfizer OEB (Section 8).

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