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

Product Identifier

Material Name: Tramadol Hydrochloride Capsules

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

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
P330 - Rinse mouth
P501 - Dispose of contents/container in accordance with all local and national regulations
SAFETY DATA SHEET

Material Name: Tramadol Hydrochloride Capsules
Revision date: 04-Apr-2015

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>
<td>Xn; R22</td>
<td>Acute Tox.3 (H301)</td>
<td>50 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>Iron oxide</td>
<td>1309-37-1</td>
<td>215-168-2</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>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>Sodium lauryl sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Iron Hydroxide</td>
<td>11113-66-9</td>
<td>234-346-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>9063-38-1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Indigotin I (E 132)</td>
<td>482-89-3</td>
<td>207-586-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
*** per tablet/capsule/lozenge/suppository
* 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.

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: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

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). 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.

**Microcrystalline cellulose**

<table>
<thead>
<tr>
<th>Material</th>
<th>ACGIH Threshold Limit Value (TWA)</th>
<th>Brazil OEL - TWA</th>
<th>France OEL - TWA</th>
<th>Germany OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Threshold Limit Value</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>6 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vietnam OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 mg/m³</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Iron oxide**

<table>
<thead>
<tr>
<th>Material</th>
<th>ACGIH Threshold Limit Value (TWA)</th>
<th>Brazil OEL - TWA</th>
<th>France OEL - TWA</th>
<th>Germany OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Threshold Limit Value</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 mg/m³</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>2 ppm</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>5.0 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>3.5 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>3.5 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>6 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>5 mg/m³</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>3.5 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>6 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>1.5 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>3.5 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Magnesium stearate**
- **ACGIH Threshold Limit Value (TWA)**: 10 mg/m³
- **Lithuania OEL - TWA**: 5 mg/m³
- **Sweden OEL - TWA**: 5 mg/m³

**Colloidal silicon dioxide**
- **Australia TWA**: 2 mg/m³
- **Austria OEL - MAKs**: 4 mg/m³
- **Czech Republic OEL - TWA**: 0.1 mg/m³
- **Estonia OEL - TWA**: 4 mg/m³
- **Germany - TRGS 900 - TWA**: 4 mg/m³
- **Germany (DFG) - MAK**: 4 mg/m³
- **Ireland OEL - TWA**: 6 mg/m³
- **Latvia OEL - TWA**: 1 mg/m³
- **OSHA - Final PELs - Table Z-3 Mineral D**: 20 mppcf
- **Slovakia OEL - TWA**: 4.0 mg/m³
- **Switzerland OEL - TWAs**: 4 mg/m³

**Titanium dioxide**
- **ACGIH Threshold Limit Value (TWA)**: 10 mg/m³
- **ACGIH OELs - Notice of Intended Changes**: Listed
- **Australia TWA**: 10 mg/m³
- **Austria OEL - MAKs**: 5 mg/m³
- **Belgium OEL - TWA**: 10 mg/m³
- **Bulgaria OEL - TWA**: 10.0 mg/m³
- **Denmark OEL - TWA**: 6 mg/m³
- **Estonia OEL - TWA**: 5 mg/m³
- **France OEL - TWA**: 10 mg/m³
- **Greece OEL - TWA**: 10 mg/m³
- **Ireland OEL - TWAs**: 10 mg/m³
- **Latvia OEL - TWA**: 10 mg/m³
- **Lithuania OEL - TWA**: 5 mg/m³
- **OSHA - Final PELs - TWAs**: 15 mg/m³
- **Poland OEL - TWA**: 10.0 mg/m³
- **Portugal OEL - TWA**: 10 mg/m³
- **Romania OEL - TWA**: 10 mg/m³
- **Russia OEL - TWA**: 10 mg/m³
- **Spain OEL - TWA**: 10 mg/m³
- **Sweden OEL - TWAs**: 5 mg/m³
- **Switzerland OEL - TWAs**: 6 mg/m³
- **Vietnam OEL - TWAs**: 5 mg/m³

**Sodium lauryl sulfate**
- **Pfizer OEL TWA-8 Hr**: 0.3 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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: Capsule
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)
Tramadol Hydrochloride Predicted 7 Log P 1.34
Iron Hydroxide No data available
Microcrystalline cellulose No data available
Iron oxide No data available
Magnesium stearate No data available
Gelatin No data available
Titanium dioxide No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Sodium starch glycolate
No data available

Sodium lauryl sulfate
No data available

Indigotin I (E 132)
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

 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: May cause eye irritation; May cause skin irritation. (based on components) May be 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

<table>
<thead>
<tr>
<th>Rat</th>
<th>Oral</th>
<th>LD50</th>
<th>228 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Para-periosteal</td>
<td>LD50</td>
<td>57.6 mg/kg</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

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)

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

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

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
11. TOXICOLOGICAL INFORMATION

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

Sodium lauryl sulfate  
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

Carcinogen Status:  See below

Iron oxide  
*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:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

**Sodium lauryl sulfate**

*Oncorhynchus mykiss* (Rainbow Trout)  
*LC50*  96 Hours  3.6 mg/L

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

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

Iron Hydroxide
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: 234-346-0

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
<table>
<thead>
<tr>
<th>Material Name: Tramadol Hydrochloride Capsules</th>
</tr>
</thead>
</table>

**15. REGULATORY INFORMATION**

<table>
<thead>
<tr>
<th>EU EINECS/ELINCS List</th>
<th>232-674-9</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Iron oxide</strong></td>
<td></td>
</tr>
<tr>
<td>CERCLA/SARA 313 Emission reporting Not Listed</td>
<td></td>
</tr>
<tr>
<td>California Proposition 65 Not Listed</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b) Present</td>
<td></td>
</tr>
<tr>
<td>Australia (AICS): Present</td>
<td></td>
</tr>
<tr>
<td>EU EINECS/ELINCS List 215-168-2</td>
<td></td>
</tr>
<tr>
<td><strong>Magnesium stearate</strong></td>
<td></td>
</tr>
<tr>
<td>CERCLA/SARA 313 Emission reporting Not Listed</td>
<td></td>
</tr>
<tr>
<td>California Proposition 65 Not Listed</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b) Present</td>
<td></td>
</tr>
<tr>
<td>Australia (AICS): Present</td>
<td></td>
</tr>
<tr>
<td>EU EINECS/ELINCS List 209-150-3</td>
<td></td>
</tr>
<tr>
<td><strong>Colloidal silicon dioxide</strong></td>
<td></td>
</tr>
<tr>
<td>CERCLA/SARA 313 Emission reporting Not Listed</td>
<td></td>
</tr>
<tr>
<td>California Proposition 65 Not Listed</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b) Present</td>
<td></td>
</tr>
<tr>
<td>Australia (AICS): Present</td>
<td></td>
</tr>
<tr>
<td>EU EINECS/ELINCS List 231-545-4</td>
<td></td>
</tr>
<tr>
<td><strong>Gelatin</strong></td>
<td></td>
</tr>
<tr>
<td>CERCLA/SARA 313 Emission reporting Not Listed</td>
<td></td>
</tr>
<tr>
<td>California Proposition 65 Not Listed</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b) Present</td>
<td></td>
</tr>
<tr>
<td>Australia (AICS): Present</td>
<td></td>
</tr>
<tr>
<td>EU EINECS/ELINCS List 232-554-6</td>
<td></td>
</tr>
<tr>
<td><strong>Titanium dioxide</strong></td>
<td></td>
</tr>
<tr>
<td>CERCLA/SARA 313 Emission reporting Not Listed</td>
<td></td>
</tr>
<tr>
<td>California Proposition 65 Not Listed</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b) Present</td>
<td></td>
</tr>
<tr>
<td>Australia (AICS): Present</td>
<td></td>
</tr>
<tr>
<td>EU EINECS/ELINCS List 236-675-5</td>
<td></td>
</tr>
<tr>
<td><strong>Sodium starch glycolate</strong></td>
<td></td>
</tr>
<tr>
<td>CERCLA/SARA 313 Emission reporting Not Listed</td>
<td></td>
</tr>
<tr>
<td>California Proposition 65 Not Listed</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b) Present</td>
<td></td>
</tr>
<tr>
<td>Australia (AICS): Present</td>
<td></td>
</tr>
<tr>
<td>EU EINECS/ELINCS List Not Listed</td>
<td></td>
</tr>
<tr>
<td><strong>Sodium lauryl sulfate</strong></td>
<td></td>
</tr>
<tr>
<td>CERCLA/SARA 313 Emission reporting Not Listed</td>
<td></td>
</tr>
<tr>
<td>California Proposition 65 Not Listed</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b) Present</td>
<td></td>
</tr>
<tr>
<td>Australia (AICS): Present</td>
<td></td>
</tr>
<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 6</td>
<td></td>
</tr>
</tbody>
</table>
15. REGULATORY INFORMATION

| EU EINECS/ELINCS List | 205-788-1 |

Indigotin I (E 132)
- 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: 207-586-9

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 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 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. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet