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

Product Identifier

Material Name: Doxycycline Hyclate Tablets
Trade Name: VIBRA-TABS; VIBRAMYCIN; BASSADO
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as antibiotic agent

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
Reproductive Toxicity: Category 1A

EU Classification:
EU Indication of danger: Toxic to reproduction: Category 1
EU Risk Phrases:
R61 - May cause harm to the unborn child.

Label Elements

Signal Word: Danger
Hazard Statements: H360D - May damage the unborn child

Precautionary Statements:
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
SAFETY DATA SHEET

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Other Hazards
Australian Hazard Classification (NOHSC):

No data available

Note:
This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous</th>
<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></td>
<td>Doxycycline hyclate</td>
<td>24390-14-5</td>
<td>Not Listed</td>
<td>Repr.Cat 1;R61</td>
<td>Repr. 1A (H360D)</td>
<td>50-60</td>
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<tr>
<td></td>
<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></td>
<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></td>
<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></td>
<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></td>
<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></td>
<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>
</tbody>
</table>

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.

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: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
SAFETY DATA SHEET

Material Name: Doxycycline Hyclate Tablets
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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:
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 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**

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

**Doxycycline Hyclate**

- **Pfizer OEL TWA-8 Hr:** 250µg/m³

**Propylene glycol**

- **Australia TWA:**
  - 150 ppm
  - 474 mg/m³
  - 10 mg/m³
- **Ireland OEL - TWAs:**
  - 150 ppm
  - 470 mg/m³
  - 10 mg/m³
- **Latvia OEL - TWA:**
  - 7 mg/m³
- **Lithuania OEL - TWA:**
  - 7 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
  - 5 mg/m³
- **Ireland OEL - TWAs:**
  - 10 mg/m³
  - 4 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:**
  - 3 mg/m³
- **Vietnam OEL - TWAs:**
  - 6 mg/m³
  - 5 mg/m³

**Magnesium Stearate**

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

**Microcrystalline cellulose**

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

**Sodium lauryl sulfate**

<table>
<thead>
<tr>
<th>Country</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer OEL TWA-8 Hr:</td>
<td>0.3 mg/m³</td>
</tr>
</tbody>
</table>

**Talc (non-asbestiform)**

<table>
<thead>
<tr>
<th>Country</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>2.5 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>2 mg/m³</td>
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<tr>
<td>Belgium OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>1.0 fiber/cm³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>2.0 mg/m³</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>0.3 fiber/cm³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>0.5 fiber/cm³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>0.25 mg/m³</td>
</tr>
<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>Portugal OEL - TWA</td>
<td>1.0 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>
<tr>
<td>Slovenia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

**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 airborne contamination levels below the exposure limits listed above in this section.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Personal Protective Equipment:</th>
<th>Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hands:</td>
<td>Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.</td>
</tr>
<tr>
<td>Eyes:</td>
<td>Wear safety glasses or goggles if eye contact is possible.</td>
</tr>
<tr>
<td>Skin:</td>
<td>Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.</td>
</tr>
<tr>
<td>Respiratory protection:</td>
<td>If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.</td>
</tr>
</tbody>
</table>

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>Odorless</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>Salmon colored</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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) No data available
Magnesium Stearate No data available
Doxycycline hyclate No data available
Talc (non-asbestiform) No data available
Titanium dioxide No data available
Hydroxypropyl methylcellulose No data available
Ethylcellulose No data available
Microcrystalline cellulose No data available
Sodium lauryl sulfate No data available
FD&C Yellow No. 6 Lake No data available
Propylene glycol 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: No data available
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
SAFETY DATA SHEET

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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
Polymerization: Will not occur

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.
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: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: May cause allergic reactions in susceptible individuals. Accidental ingestion may cause effects similar to those seen in clinical use.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.
Known Clinical Effects: May cause permanent discoloration of teeth if used during tooth development. May cause effects similar to those generally seen in clinical use of tetracyclines including gastrointestinal irritation, nausea, vomiting, and diarrhea. Photosensitivity has been reported in some individuals taking tetracyclines.

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

Doxycycline hyclate
Mouse Oral LD50 1900 mg/kg (hydrochloride)
Rat Oral LD50 > 2000mg/kg (hydrochloride)
Rat Intravenous LD50 228mg/kg (hydrochloride)
Rat (weanling) Intraperitoneal LD50 262mg/kg (hydrochloride)

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

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

Hydroxypropyl methylcellulose
Rat Oral LD50 > 10,000 mg/kg

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Sodium lauryl sulfate
Rat Oral LD50 1288 mg/kg
### 11. TOXICOLOGICAL INFORMATION

**Propylene glycol**
- Rat Oral LD 50 22,000 mg/kg
- Mouse Oral LD 50 24,900 mg/kg
- Rabbit Dermal LD 50 20,800 mg/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
- Sodium lauryl sulfate
  - Eye Irritation Rabbit Moderate
  - Skin Irritation Rabbit Mild Moderate
  - Skin Sensitization - GPMT Guinea Pig Negative
  - Skin Sensitization - LLNA Mouse Negative
- Propylene glycol
  - Skin Irritation Rabbit Mild
  - Eye Irritation Rabbit Mild

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**
- Magnesium Stearate
  - 13 Week(s) Rat Oral 1092 g/kg LOAEL Liver
- Doxycycline hyclate
  - 30 Day(s) Rat Oral 500 mg/kg NOEL None identified
  - 18 Month(s) Rat Oral 50 mg/kg/day NOEL Thyroid, Bone
  - 1 Year(s) Dog Oral < 10 mg/kg/day NOEL Liver

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**
- Doxycycline hyclate
  - Reproductive & Fertility-Females Rat Oral 250 mg/kg/day NOEL No effects at maximum dose
  - Embryo / Fetal Development Monkey Oral 50 mg/kg/day NOEL No effects at maximum dose

**Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**
- Sodium lauryl sulfate
  - Bacterial Mutagenicity (Ames) *Salmonella* Negative

**Carcinogen Status:** See below

**Talc (non-asbestiform)**
- IARC: Group 3 (Not Classifiable)
11. TOXICOLOGICAL INFORMATION

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. 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: No data available

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:**  
Class D, Division 2, Subdivision A

<table>
<thead>
<tr>
<th>Material Name</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS)</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doxycycline hyclate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Developmental toxicity initial date 10/1/91 internal use</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Ethylcellulose</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>200-338-0</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Carcinogen initial date 9/2/11 airborne, unbound particles of respirable size</td>
<td>Present</td>
<td>236-675-5</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>209-150-3</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>232-674-9</td>
</tr>
</tbody>
</table>

**California Proposition 65**  
Carcinogen initial date 10/1/91 airborne, unbound particles of respirable size

**EU EINECS/ELINCS List**

**Version:** 6.0
15. REGULATORY INFORMATION

Sodium lauryl sulfate
- 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 6
  EU EINECS/ELINCS List: 205-788-1

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

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

FD&C Yellow No. 6 Lake
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

16. OTHER INFORMATION

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

Reproductive toxicity-Cat.1A; H360D - May damage the unborn child

Toxic to reproduction: Category 1

R61 - May cause harm to the unborn child.

Data Sources:
Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision:
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

Revision date: 13-Mar-2015

Prepared by:
Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations
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