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

Product Identifier
Material Name: Varenicline tartrate tablets
Trade Name: CHANTIX; CHAMPIX
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product used for Smoking cessation

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification Not classified as hazardous

Label Elements
Signal Word: Not required
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards
Note: No data available
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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

PZ00325
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varenicline tartrate</td>
<td>375815-87-5</td>
<td>Not Listed</td>
<td>Acute Tox.4 (H302) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)</td>
<td>&lt;1.0</td>
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<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
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<tr>
<td>Film coating</td>
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</tr>
<tr>
<td>Calcium phosphate dibasic, anhydrous</td>
<td>7757-93-9</td>
<td>231-826-1</td>
<td>Not Listed</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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<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</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 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.

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

PZ00325
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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
Latvia OEL - TWA 4 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³
Vietnam OEL - TWAs 10 mg/m³
  5 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Calcium phosphate dibasic, anhydrous
   Latvia OEL - TWA  10 mg/m³

Varenicline tartrate
   Pfizer OEL TWA-8 Hr:  5 µg/m³

Colloidal silicon dioxide
   Australia TWA  2 mg/m³
   Austria OEL - MAKs  4 mg/m³
       0.3 mg/m³
   Czech Republic OEL - TWA  0.1 mg/m³
       4.0 mg/m³
   Estonia OEL - TWA  2 mg/m³
   Finland OEL - TWA  5 mg/m³
   Germany - TRGS 900 - TWAs  4 mg/m³
   Germany (DFG) - MAK  4 mg/m³
   Ireland OEL - TWAs  6 mg/m³
       2.4 mg/m³
   Latvia OEL - TWA  1 mg/m³
   OSHA - Final PELs - Table Z-3 Mineral D:  20 mppcf
       Listed
   Slovakia OEL - TWA  4.0 mg/m³
   Switzerland OEL -TWAs  4 mg/m³
       0.3 mg/m³

Magnesium stearate
   ACGIH Threshold Limit Value (TWA)  10 mg/m³
   Lithuania OEL - TWA  5 mg/m³
   Sweden OEL - TWAs  5 mg/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 airborne
                        contamination levels below the exposure limits 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:  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.
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Film-coated tablets</td>
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<tr>
<td>Odor</td>
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</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
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<td>Water Solubility</td>
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<tr>
<td>pH</td>
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<tr>
<td>Melting/Freezing Point (°C)</td>
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<tr>
<td>Boiling Point (°C)</td>
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<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
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<tr>
<td>Decomposition Temperature (°C)</td>
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<tr>
<td>Evaporation Rate (Gram/s)</td>
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<td>Vapor Pressure (kPa)</td>
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<tr>
<td>Vapor Density (g/ml)</td>
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<td>Relative Density</td>
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<td>Viscosity</td>
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<td>Flammability</td>
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<td>Autoignition Temperature (Solid) (°C)</td>
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<td>Flammability (Solids)</td>
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<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.)</td>
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10. STABILITY AND REACTIVITY

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<th>Property</th>
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</thead>
<tbody>
<tr>
<td>Reactivity</td>
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<tr>
<td>Chemical Stability</td>
<td>Stable under normal conditions of use</td>
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<tr>
<td>Possibility of Hazardous Reactions</td>
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<td>Oxidizing Properties</td>
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<tr>
<td>Conditions to Avoid</td>
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<tr>
<td>Incompatible Materials</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
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</tr>
</tbody>
</table>
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: Active ingredient may be harmful if swallowed. May cause minor irritation if tablets are crushed or broken.

Long Term: Animal studies indicate that this material may cause adverse effects on the liver.

Known Clinical Effects: Adverse effects associated with therapeutic use include nausea, sleep disturbances, constipation, flatulence, vomiting. Additionally, behavioral changes, agitation, depressive mood, suicidal behavior, abnormal dreams, and effects on cardiovascular system may occur.

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

| Microcrystalline cellulose | Rat Oral LD50 > 5000 mg/kg | Rabbit Dermal LD50 > 2000 mg/kg |
| Varenicline tartrate | Rat Oral LDmin.(hydrochloride salt) 300 mg/kg | Rat Dermal LD50 > 2000 mg/kg |
| Magnesium stearate | Rat Oral LD50 > 2000 mg/kg | Rat Inhalation LC50 > 2000 mg/m³ |

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 |
| Varenicline tartrate | Eye Irritation Rabbit Mild | Skin Irritation Rabbit Mild |
| | Skin Sensitization - M & K Guinea Pig Negative |

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

| Varenicline tartrate | 3 Month(s) Monkey Oral 0.2 mg/kg/day NOAEL No effects at maximum dose | 9 Month(s) Monkey Oral 0.2 mg/kg/day NOAEL No effects at maximum dose |
| | 3 Month(s) Rat Oral 10 mg/kg/day NOAEL Gastrointestinal system, Liver | 6 Month(s) Rat Oral 10 mg/kg/day NOAEL Gastrointestinal system |
| | 9 Month(s) Monkey Oral 0.4 mg/kg/day NOAEL Gastrointestinal system |

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

| Varenicline tartrate | Fertility & Embryonic Development - Females Rat Oral15 mg/kg/day NOAEL No effects at maximum dose |
11. TOXICOLOGICAL INFORMATION

Fertility & Embryonic Development - Males  Rat  Oral  15 mg/kg/day  NOAEL  No effects at maximum dose
Embryo / Fetal Development  Rat  Oral  0.3 mg/kg/day  NOAEL  Maternal Toxicity, Not Teratogenic
Embryo / Fetal Development  Rabbit  Oral  10 mg/kg/day  NOAEL  Maternal Toxicity, Fetotoxicity
Prenatal & Postnatal Development  Rat  Oral  0.3, 3 mg/kg/day  NOAEL  Maternal Toxicity, Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Varenicline tartrate
Bacterial Mutagenicity (Ames)  *Salmonella*, *E. coli*  Negative
*In Vitro* Chromosome Aberration  Chinese Hamster Ovary (CHO) cells  Negative
*In Vitro* Chromosome Aberration  Human Lymphocytes  Negative
*In Vivo* Micronucleus  Rat Bone Marrow  Negative

Varenicline tartrate
2 Year(s)  Rat Male  Oral  1 mg/kg/day  NOAEL  Tumors
2 Year(s)  Mouse  Oral  20 mg/kg/day  NOEL  Not carcinogenic

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Colloidal silicon dioxide
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:  This mixture contains material that is toxic to aquatic life. Releases to the environment should be avoided.

Toxicity:

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

Varenicline tartrate
*Oncorhynchus mykiss* (Rainbow Trout)  OECD  LC50  96 Hours  48 mg/L
*Pseudokirchneriella subcapitata* (Green Alga)  OECD  EC50  72 Hours  2.9 mg/L
*Polytox*  OECD  MIC  3 Hours  > 100 mg/L
*Daphnia magna* (Water Flea)  OECD  EC50  48 Hours  0.24 mg/L

Aquatic Toxicity Comments:  A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Varenicline tartrate
*Trichoderma viride* (Fungus)  MIC  > 1000 mg/L
*Bacillus subtilis* (Bacterium)  MIC  > 1000 mg/L

Persistence and Degradability:

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Varenicline tartrate
OECD  Activated sludge  Ultimate (CO2 Evolution)  15.7% After  28 Day(s)  Not Ready

Bio-accumulative Potential:
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

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

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

Calcium phosphate dibasic, anhydrous
- CERCLA/SARA 313 Emission reporting: Not Listed
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</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>
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<tbody>
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<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>231-826-1</td>
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<tr>
<td>Colloidal silicon dioxide</td>
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<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>231-545-4</td>
</tr>
<tr>
<td>Magnesium stearate</td>
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<td>Present</td>
<td>Present</td>
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<td>Croscarmellose sodium</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

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 11 - Toxicology Information. Updated Section 16 - Other Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients.

Revision date: 13-May-2016
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