SAFETY DATA SHEET

Revision date: 10-Mar-2015
Version: 3.0
Page 1 of 10

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

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: Not classified as hazardous

EU Classification:
EU Indication of danger: Not classified

Label Elements
Signal Word: Not required

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>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>PZ00325</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
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Revision date: 10-Mar-2015

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>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>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
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<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Varenicline tartrate</td>
<td>375815-87-5</td>
<td>Not Listed</td>
<td>N;R50/53 Xn;R22</td>
<td>Acute Tox.4 (H302) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)</td>
<td>&lt;1.0</td>
</tr>
<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>Film coating</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Calcium phosphate dibasic, anhydrous</td>
<td>7757-93-9</td>
<td>231-826-1</td>
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<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>Not Listed</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.
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. 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.

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
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Analytical Method:**
Analytical method available for Varenicline. Contact Pfizer Inc for further information.

**Exposure 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>
<td>Molecular Formula</td>
<td>Mixture</td>
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<tr>
<td>Solvent Solubility</td>
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<tr>
<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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</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
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<tr>
<td>Decomposition Temperature (°C)</td>
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</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
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<td>Vapor Pressure (kPa)</td>
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<td>Relative Density</td>
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<td>Viscosity</td>
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<tr>
<td>Flammability</td>
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<td>Autoignition Temperature (Solid) (°C)</td>
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<tr>
<td>Flammability (Solids)</td>
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<tr>
<td>Flash Point (Liquid) (°C)</td>
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<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.)</td>
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</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.)</td>
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</tr>
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</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>No data available</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 Oral 15 mg/kg/day NOAEL No effects at maximum dose
11. TOXICOLOGICAL INFORMATION

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
Polytot 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:
Partition Coefficient: (Method, pH, Endpoint, Value)
Varenicline tartrate
Measured 6-8 Log D -0.817

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:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

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

Magnesium stearate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b) | Present
Australia (AICS): | Present
EU EINECS/ELINCS List | 209-150-3

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
California Proposition 65 | Not Listed
Inventory - United States TSCA - Sect. 8(b) | Present
Australia (AICS): | Present
EU EINECS/ELINCS List | 231-826-1

Varenicline tartrate

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

Croskarmellose sodium

CERCLA/SARA 313 Emission reporting | Not Listed
California Proposition 65 | Not Listed
Australia (AICS): | Present
EU EINECS/ELINCS List | Not Listed

16. OTHER INFORMATION

Text of R phrases and 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

N - Dangerous for the environment
Xn - Harmful
R22 - Harmful if swallowed.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

Revision date: 10-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