



# SAFETY DATA SHEET

Revision date: 13-May-2016

Version: 3.1

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## 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:  
International CHEMTREC (24 hours): +1-703-527-3887

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

### 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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Varenicline tartrate	375815-87-5	Not Listed	Acute Tox.4 (H302) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	<1.0
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Film coating	NOT ASSIGNED	Not Listed	Not Listed	*
Calcium phosphate dibasic, anhydrous	7757-93-9	231-826-1	Not Listed	*
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*

**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**

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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/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	2 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Russia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL - TWAs	3 mg/m <sup>3</sup>
Vietnam OEL - TWAs	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Calcium phosphate dibasic, anhydrous

Latvia OEL - TWA 10 mg/m<sup>3</sup>

#### Varenicline tartrate

Pfizer OEL TWA-8 Hr: 5 µg/m<sup>3</sup>

#### Colloidal silicon dioxide

Australia TWA 2 mg/m<sup>3</sup>

Austria OEL - MAKs 4 mg/m<sup>3</sup>

0.3 mg/m<sup>3</sup>

Czech Republic OEL - TWA 0.1 mg/m<sup>3</sup>

4.0 mg/m<sup>3</sup>

Estonia OEL - TWA 2 mg/m<sup>3</sup>

Finland OEL - TWA 5 mg/m<sup>3</sup>

Germany - TRGS 900 - TWAs 4 mg/m<sup>3</sup>

Germany (DFG) - MAK 4 mg/m<sup>3</sup>

Ireland OEL - TWAs 6 mg/m<sup>3</sup>

2.4 mg/m<sup>3</sup>

Latvia OEL - TWA 1 mg/m<sup>3</sup>

OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf

Listed

Slovakia OEL - TWA 4.0 mg/m<sup>3</sup>

Switzerland OEL - TWAs 4 mg/m<sup>3</sup>

0.3 mg/m<sup>3</sup>

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

Sweden OEL - TWAs 5 mg/m<sup>3</sup>

#### Analytical Method:

Analytical method available for Varenicline. Contact Pfizer Inc for further information.

#### 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.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Film-coated tablets	<b>Color:</b>	White to off-white ; Blue
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	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)**

**Calcium phosphate dibasic, anhydrous**

No data available

**Croscarmellose sodium**

No data available

**Colloidal silicon dioxide**

No data available

**Film coating**

No data available

**Microcrystalline cellulose**

No data available

**Varenicline tartrate**

Measured 6-8 Log D -0.817

**Magnesium stearate**

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

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### 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 > 2000mg/kg

##### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### 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

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### 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 (CO<sub>2</sub> Evolution) 15.7% After 28 Day(s) Not Ready

#### Bio-accumulative Potential:

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**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**

**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
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### 15. REGULATORY INFORMATION

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

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

#### Croscarmellose 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 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  
Product Stewardship Hazard Communication

**Prepared by:** 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.

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**End of Safety Data Sheet**