



MATERIAL SAFETY DATA SHEET

Revision date: 26-Jul-2011

Version: 2.2

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

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Material Name: Varenicline tartrate tablets

Trade Name: CHANTIX; CHAMPIX
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for Smoking cessation

2. HAZARDS IDENTIFICATION

Appearance: White to off-white film-coated tablets; Blue film-coated tablets

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

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.

EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
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	N;R50/53 Xn;R22	<1.0
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Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Colloidal silicon dioxide	7631-86-9	231-545-4 418-260-2	Not Listed	*
Film coating	NOT ASSIGNED	Not Listed	Not Listed	*
Calcium phosphate dibasic, anhydrous	7757-93-9	231-826-1	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.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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.

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Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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

General 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Colloidal silicon dioxide

Australia TWA	2 mg/m ³
Austria OEL - MAKs	4 mg/m ³
Czech Republic OEL - TWA	0.1 mg/m ³
	4.0 mg/m ³
Estonia OEL - TWA	2 mg/m ³
Germany - TRGS 900 - TWAs	4 mg/m ³
Germany (DFG) - MAK	4 mg/m ³ inhalable fraction
Ireland OEL - TWAs	6 mg/m ³
	2.4 mg/m ³
Latvia OEL - TWA	1 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m ³
Slovenia OEL - TWA	4 mg/m ³

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	2 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³

Calcium phosphate dibasic, anhydrous

Latvia OEL - TWA	10 mg/m ³
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Varenicline tartrate

Pfizer OEL TWA-8 Hr:	5 µg/m ³
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Analytical Method:	Analytical method available for Varenicline. Contact Pfizer Inc for further information.
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.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
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

Physical State:	Film-coated tablets	Color:	White to off-white ; Blue
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal conditions of use.
Conditions to Avoid:	None known
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information:	The information included in this section describes the potential hazards of the individual ingredients.
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Acute Toxicity: (Species, Route, End Point, Dose)

Microcrystalline cellulose

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

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11. TOXICOLOGICAL INFORMATION

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 NOEL No effects at maximum dose
9 Month(s) Monkey Oral 0.2 mg/kg/day NOEL No effects at maximum dose
3 Month(s) Rat Oral 10 mg/kg/day NOEL Gastrointestinal system, Liver
6 Month(s) Rat Oral 10 mg/kg/day NOEL Gastrointestinal system
9 Month(s) Monkey Oral 0.4 mg/kg/day NOEL 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 NOEL No effects at maximum dose
Fertility & Embryonic Development - Males Rat Oral 15 mg/kg/day NOEL No effects at maximum dose
Embryo / Fetal Development Rat Oral 0.3 mg/kg/day NOEL Maternal Toxicity, Not Teratogenic
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day NOEL Maternal Toxicity, Fetotoxicity
Prenatal & Postnatal Development Rat Oral 0.3, 3 mg/kg/day NOEL 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 NOEL 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.

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11. TOXICOLOGICAL INFORMATION

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.

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

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

EU Indication of danger: Not classified

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15. REGULATORY INFORMATION

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

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

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4 418-260-2

Magnesium stearate

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

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9

Calcium phosphate dibasic, anhydrous

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-826-1

Croscarmellose sodium

Australia (AICS):	Present
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16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R50 - Very toxic to aquatic organisms.

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 8 - Exposure Controls / Personal Protection.

Prepared by:

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

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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