



MATERIAL SAFETY DATA SHEET

Revision date: 23-Oct-2011

Version: 5.0

Page 1 of 11

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

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

Material Name: Pristiq Tablets

Trade Name:	PRISTIQ
Synonyms:	Desvenlafaxine Succinate Extended Release Tablets
Chemical Family:	Serotonin Noradrenaline Reuptake Inhibitor
Intended Use:	Pharmaceutical product used as antidepressant

2. HAZARDS IDENTIFICATION

Appearance: Tablet
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.

Additional Hazard Information:

Short Term: Individuals taking monoamine oxidase (MAO) inhibitors should avoid exposure to this material.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.
Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, insomnia, nausea, constipation, vomiting, dry mouth, nervousness, anxiety, tremors, impotence, abnormal dreams, abnormal ejaculation, and sweating. Signs and symptoms associated with non-fatal overdose were drowsiness, vomiting, rapid heart rate, nausea, dizziness, agitation, and tremor.

EU Indication of danger: Harmful

EU Hazard Symbols:



EU Risk Phrases:

R22 - Harmful if swallowed.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

MATERIAL SAFETY DATA SHEET

Material Name: Pristiq Tablets
Revision date: 23-Oct-2011

Page 2 of 11
Version: 5.0

2. HAZARDS IDENTIFICATION

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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Desvenlafaxine Succinate Monohydrate	386750-22-7	Not Listed	Xn;R22	50-200mg***
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Iron oxide	1309-37-1	215-168-2	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Polyvinyl alcohol	9002-89-5	Not Listed	Not Listed	*

Additional Information: * Proprietary
*** per tablet/capsule/lozenge/suppository
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.

MATERIAL SAFETY DATA SHEET

Material Name: Pristiq Tablets
Revision date: 23-Oct-2011

Page 3 of 11
Version: 5.0

Fire / Explosion Hazards: Strong dust explosion characteristic. High sensitivity of a dust cloud to ignition, based on minimum ignition energy.

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 spill with absorbent material. Clean spill area thoroughly. Avoid use of a filtered vacuum to clean spills of dry solids, due to the potential for electrostatic discharge and the strong dust explosion characteristic and high sensitivity to ignition.

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. 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.

Desvenlafaxine Succinate Monohydrate

Pfizer OEL TWA-8 Hr: 350µg/m³

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

4 mg/m³

Latvia OEL - TWA 2 mg/m³

OSHA - Final PELs - TWAs: 15 mg/m³

Portugal OEL - TWA 10 mg/m³

Romania OEL - TWA 10 mg/m³

Spain OEL - TWA 10 mg/m³

Iron oxide

ACGIH Threshold Limit Value (TWA) 5 mg/m³

MATERIAL SAFETY DATA SHEET

Material Name: Pristiq Tablets
Revision date: 23-Oct-2011

Page 4 of 11
Version: 5.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	5 mg/m ³
Austria OEL - MAKs	5 mg/m ³
	10 mg/m ³
Belgium OEL - TWA	2 ppm
	5 mg/m ³
Denmark OEL - TWA	3.5 mg/m ³
Estonia OEL - TWA	3.5 mg/m ³
Finland OEL - TWA	5 mg/m ³
France OEL - TWA	5 mg/m ³
Greece OEL - TWA	10 mg/m ³
Hungary OEL - TWA	6 mg/m ³
Ireland OEL - TWAs	5 mg/m ³
	10 mg/m ³
	4 mg/m ³
Lithuania OEL - TWA	3.5 mg/m ³
OSHA - Final PELs - TWAs:	10 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 mg/m ³
Romania OEL - TWA	5 mg/m ³
Slovakia OEL - TWA	1.5 mg/m ³
Spain OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	3.5 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
Polyethylene glycol	
Austria OEL - MAKs	1000 mg/m ³
Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ inhalable fraction
Slovakia OEL - TWA	1000 mg/m ³
Slovenia OEL - TWA	1000 mg/m ³
Titanium dioxide	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Austria OEL - MAKs	5 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Denmark OEL - TWA	6 mg/m ³
Estonia OEL - TWA	5 mg/m ³
France OEL - TWA	10 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10.0 mg/m ³

MATERIAL SAFETY DATA SHEET

Material Name: Pristiq Tablets
Revision date: 23-Oct-2011

Page 5 of 11
Version: 5.0

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
Sweden OEL - TWAs	5 mg/m ³

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	2 mg/m ³
Australia TWA	2.5 mg/m ³
Austria OEL - MAKs	2 mg/m ³
Belgium OEL - TWA	2 mg/m ³
Bulgaria OEL - TWA	1.0 fiber/cm ³
	6.0 mg/m ³
	3.0 mg/m ³
Czech Republic OEL - TWA	2.0 mg/m ³
	10 mg/m ³
Denmark OEL - TWA	0.3 fiber/cm ³
Finland OEL - TWA	0.5 fiber/cm ³
	5 mg/m ³
Greece OEL - TWA	10 mg/m ³
	2 mg/m ³
Hungary OEL - TWA	2 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	0.8 mg/m ³
Lithuania OEL - TWA	2 mg/m ³
	1 mg/m ³
Netherlands OEL - TWA	0.25 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m ³
	1.0 mg/m ³
Portugal OEL - TWA	2 mg/m ³
Romania OEL - TWA	2 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
	10 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Spain OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	2 mg/m ³
	1 mg/m ³

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.

MATERIAL SAFETY DATA SHEET

Material Name: Pristiq Tablets
Revision date: 23-Oct-2011

Page 6 of 11
Version: 5.0

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablets	Color:	Various
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Water solubility:	30 mg/mL
Melting/Freezing Point (°C):	105
Partition Coefficient (Measured - Log Pow/Log Kow):	0.33 (desvenlafaxine succinate monohydrate)

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal conditions of use.
Conditions to Avoid:	Keep away from heat and other sources of ignition, including electrostatic discharge.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The following information describes the toxicity of a chemically-related material. The toxicities of the two materials can be expected to be similar.

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

Venlafaxine hydrochloride

Rat (M)	Oral	LD50	700 mg/kg
Rat (F)	Oral	LD50	350 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

Talc (non-asbestiform)

Rat	Oral	LD50	> 1600 mg/kg
-----	------	------	--------------

Magnesium stearate

Rat	Oral	LD50	> 2000 mg/kg
Rat	Inhalation	LC50	> 2000 mg/m ³

Titanium dioxide

Rat	Oral	LD50	> 7500 mg/kg
Rat	Subcutaneous	LD 50	50 mg/kg

Desvenlafaxine Succinate Monohydrate

Rat	IP	Minimum Lethal Dose	700 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.

MATERIAL SAFETY DATA SHEET

Material Name: Pristiq Tablets
Revision date: 23-Oct-2011

Page 7 of 11
Version: 5.0

11. TOXICOLOGICAL INFORMATION

Irritation / Sensitization: (Study Type, Species, Severity)

O-Desmethylvenlafaxine free base

Skin Corrosivity (*In vitro*, RHE) Negative
Eye Irritation (*In vitro*, BCOP) Negative
Skin Sensitization - LLNA Mouse Negative

Venlafaxine hydrochloride

Eye Irritation (*In vitro*, BCOP) Negative

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Polyethylene glycol

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Desvenlafaxine Succinate Monohydrate

Skin Corrosivity (*In vitro*, RHE) Negative
Eye Irritation (*In vitro*, BCOP) Negative
Skin Sensitization - LLNA Mouse Negative

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

Desvenlafaxine Succinate Monohydrate

6 Month(s) Rat Oral 300 mg/kg/day LOAEL None identified
9 Month(s) Dog Oral 50 mg/kg/day NOAEL No effects at maximum dose

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

O-Desmethylvenlafaxine free base

Fertility and Embryonic Development Rat Oral 30 mg/kg/day NOAEL Fertility
Fertility and Embryonic Development Rat Oral 100 mg/kg/day NOAEL Developmental toxicity

Venlafaxine hydrochloride

Reproductive & Fertility Rat Oral 8 times human dose NOAEL No effects at maximum dose
Embryo / Fetal Development Rabbit Oral 12 times human dose NOAEL Not Teratogenic
Embryo / Fetal Development Rat Oral 1.4 times human dose NOAEL Not Teratogenic, Neonatal toxicity

Desvenlafaxine Succinate Monohydrate

Fertility and Embryonic Development Rat Oral 30 mg/kg/day NOAEL Fertility
Fertility and Embryonic Development Rat Oral 100 mg/kg/day NOAEL Developmental toxicity
Embryo / Fetal Development Rabbit Oral 75 mg/kg/day NOAEL No effects at maximum dose

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

O-Desmethylvenlafaxine free base

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Micronucleus Mouse Negative
Forward Mutation Assay Chinese Hamster Ovary (CHO) cells Negative
In Vivo Chromosome Aberration Rat Equivocal

MATERIAL SAFETY DATA SHEET

Material Name: Pristiq Tablets
Revision date: 23-Oct-2011

Page 8 of 11
Version: 5.0

11. TOXICOLOGICAL INFORMATION

Venlafaxine hydrochloride

Bacterial Mutagenicity (Ames) *Salmonella* Negative
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative
In Vitro Cell Transformation Assay Mouse Negative
In Vitro Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative
In Vivo Chromosome Aberration Rat Bone Marrow Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Venlafaxine hydrochloride

18 Month(s) Mouse Oral 120 mg/kg/day NOAEL Not carcinogenic
24 Month(s) Rat Oral 120 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status:

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

Talc (non-asbestiform)

IARC: Group 3 (Not Classifiable)

Polyvinyl alcohol

IARC: Group 3 (Not Classifiable)

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)
OSHA: Listed

Iron oxide

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: The information in this section includes the potential hazards of a chemically related material. The toxicities of the two materials can be expected to be similar Toxic to aquatic organisms.

Partition Coefficient (Measured - Log Pow/Log Kow): 0.33 (desvenlafaxine succinate monohydrate)

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

Venlafaxine hydrochloride

Daphnia magna (Water Flea) EC50 48 Hours 38 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 4.8 mg/L
Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours > 100 mg/L

Desvenlafaxine Succinate Monohydrate

Daphnia magna (Water Flea) OECD EC50 48 Hours 33 mg/L
Pimephales promelas (Fathead Minnow) OECD LC50 96 Hours 9.4 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 32.2 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

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

MATERIAL SAFETY DATA SHEET

Material Name: Pristiq Tablets
Revision date: 23-Oct-2011

Page 9 of 11
Version: 5.0

12. ECOLOGICAL INFORMATION

Desvenlafaxine Succinate Monohydrate

Activated sludge OECD EC50 3 Hours > 100 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Desvenlafaxine Succinate Monohydrate

Daphnia magna (Water Flea) OECD 21 Day(s) NOEC 8.2 mg/L Reproduction

Pimephales promelas (Fathead Minnow) OECD 32 Day(s) NOEC 2.1 mg/L Growth

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 Symbol: Xn
EU Indication of danger: Harmful

EU Risk Phrases:
R22 - Harmful if swallowed.

EU Safety Phrases:
S22 - Do not breathe dust.

OSHA Label:
WARNING
Harmful if swallowed.

Canada - WHMIS: Classifications

MATERIAL SAFETY DATA SHEET

Material Name: Pristiq Tablets
Revision date: 23-Oct-2011

Page 10 of 11
Version: 5.0

15. REGULATORY INFORMATION

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.

Hydroxypropyl methylcellulose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

Microcrystalline cellulose

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

Iron oxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	215-168-2

Magnesium stearate

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

Polyvinyl alcohol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

Polyethylene glycol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

Data Sources: Pfizer proprietary drug development information.

MATERIAL SAFETY DATA SHEET

Material Name: Pristiq Tablets
Revision date: 23-Oct-2011

Page 11 of 11
Version: 5.0

Reasons for Revision:

Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on
Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 7 -
Handling and Storage. Updated Section 12 - Ecological Information.

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