SAFETY DATA SHEET

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

Product Identifier

Material Name: Pristiq Tablets

Trade Name:	PRISTIQ; ECENZE; ELLEFORE; ENZUDE; EXSIRA
Synonyms:	Desvenlafaxine Succinate Extended Release Tablets
Chemical Family:	Serotonin Noradrenaline Reuptake Inhibitor

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antidepressant

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

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity: Category 4
Acute aquatic toxicity: Category 3

Label Elements

Signal Word:	Warning
Hazard Statements:	H302 - Harmful if swallowed H402 - Harmful to aquatic life
Precautionary Statements:	P264 - Wash hands thoroughly after handling P270 - Do not eat, drink or smoke when using this product P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell P330 - Rinse mouth P273 - Avoid release to the environment P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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	GHS Classification	%
Desvenlafaxine Succinate Monohydrate	386750-22-7	Not Listed	Acute Tox.4 (H302) Aquatic Acute 3 (H402)	45
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	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Polyvinyl alcohol	9002-89-5	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: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

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

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

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 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.

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. 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.

Desvenlafaxine Succinate Monohydrate

Pfizer OEL TWA-8 Hr:	350µg/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
Portugal OEL - TWA	10 mg/m^3
Romania OEL - TWA	10 mg/m^3
Russia OEL - TWA	6 mg/m^3
Spain OEL - TWA	10 mg/m^3
Switzerland OEL -TWAs	3 mg/m^3
Vietnam OEL - TWAs	10 mg/m^3 5 mg/m^3

Iron oxide

ACGIH Threshold Limit Value (TWA)	5 mg/m^3
Australia TWA	5 mg/m^3 10 mg/m^3
Austria OEL - MAKs	5 mg/m^3 10 mg/m^3
Belgium OEL - TWA	5 mg/m^3
Bulgaria OEL - TWA	5.0 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 15 mg/m^3
Poland OEL - TWA	5 mg/m^3
Portugal OEL - TWA	5 mg/m^3
Romania OEL - TWA	5 mg/m^3
Russia OEL - TWA	6 mg/m^3
Slovakia OEL - TWA	1.5 mg/m^3
Spain OEL - TWA	5 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sweden OEL - TWAs	3.5 mg/m^3
Switzerland OEL -TWAs	3 mg/m^3
Vietnam OEL - TWAs	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 average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m^3
Slovenia OEL - TWA	1000 mg/m^3
Switzerland OEL -TWAs	1000 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/cm3 6.0 mg/m^3 3.0 mg/m^3
Czech Republic OEL - TWA	2.0 mg/m^3
Denmark OEL - TWA	0.3 fiber/cm3
Finland OEL - TWA	0.5 fiber/cm3
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
Switzerland OEL -TWAs	2 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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
Portugal OEL - TWA	10 mg/m^3
Romania OEL - TWA	10 mg/m^3
Russia OEL - TWA	10 mg/m^3
Spain OEL - TWA	10 mg/m^3
Sweden OEL - TWAs	5 mg/m^3
Switzerland OEL -TWAs	3 mg/m^3
Vietnam OEL - TWAs	6 mg/m^3 5 mg/m^3

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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Hands:	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Respiratory protection:	Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablets	**Color:**	Various
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility:	No data available
Water solubility:	30 mg/mL

9. PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): 105
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Venlafaxine hydrochloride
Measured Log P 0.5
Polyvinyl alcohol
No data available
Titanium dioxide
No data available
Iron oxide
No data available
Polyethylene glycol
No data available
Hydroxypropyl methylcellulose
No data available
Magnesium stearate
No data available
O-Desmethylvenlafaxine free base
Predicted 7.0 Log P 2.26
Microcrystalline cellulose
No data available
Desvenlafaxine Succinate Monohydrate
Measured 6.0 Log P 0.33
Talc (non-asbestiform)
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

Flammablity:
- **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

Polymerization: Will not occur

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:** Keep away from heat and other sources of ignition, including electrostatic discharge.
- **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
- **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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.

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 overdosage were drowsiness, vomiting, rapid heart rate, nausea, dizziness, agitation, and tremor.

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

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

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD50 50 mg/kg

Hydroxypropyl methylcellulose
Rat Oral LD50 > 10,000 mg/kg

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

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

Desvenlafaxine Succinate Monohydrate
Rat IP Minimum Lethal Dose 700 mg/kg

Talc (non-asbestiform)
Rat Oral LD50 > 1600 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.

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

Venlafaxine hydrochloride
Eye Irritation (*In vitro* , BCOP) Negative

Polyethylene glycol
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

O-Desmethylvenlafaxine free base
Skin Corrosivity (*In vitro* , RHE) Negative

11. TOXICOLOGICAL INFORMATION

Eye Irritation (*In vitro* , BCOP) Negative
Skin Sensitization - LLNA Mouse Negative
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Negative

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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 Oral300 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))

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

O-Desmethylvenlafaxine free base
Fertility and Embryonic Development Rat Oral30 mg/kg/day NOAEL Fertility
Fertility and Embryonic Development Rat Oral 100 mg/kg/day NOAEL Developmental toxicity

Desvenlafaxine Succinate Monohydrate
Fertility and Embryonic Development Rat Oral30 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)

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

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

11. TOXICOLOGICAL INFORMATION

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.

Polyvinyl alcohol
IARC: Group 3 (Not Classifiable)

Titanium dioxide
IARC: Group 2B (Possibly Carcinogenic to Humans)

Iron oxide
IARC: Group 3 (Not Classifiable)

Talc (non-asbestiform)
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.

Toxicity:

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)

Desvenlafaxine Succinate Monohydrate
Activated sludge OECD EC50 > 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
Chironomus riparius (Sediment-Dwelling Midges) OECD 28 Day(s) NOEC 52 mg/kg

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available
Partition Coefficient: (Method, pH, Endpoint, Value)
Venlafaxine hydrochloride
Measured Log P 0.5
O-Desmethylvenlafaxine free base
Predicted 7.0 Log P 2.26
Desvenlafaxine Succinate Monohydrate
Measured 6.0 Log P 0.33

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

Desvenlafaxine Succinate Monohydrate

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

Hydroxypropyl methylcellulose

15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

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
EU EINECS/ELINCS List	232-674-9

Iron oxide

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	215-168-2

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

Polyvinyl alcohol

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	Not Listed

Polyethylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 3
EU EINECS/ELINCS List	Not Listed

Talc (non-asbestiform)

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	238-877-9

15. REGULATORY INFORMATION

Titanium dioxide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen 9/2/2011 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

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.3; H402 - Harmful to aquatic life

Data Sources:	Pfizer proprietary drug development information.
Reasons for Revision:	Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.
Revision date:	26-Jan-2017
	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.

End of Safety Data Sheet