



# SAFETY DATA SHEET

Revision date: 10-Nov-2014

Version: 2.0

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

### Product Identifier

**Material Name:** Bazedoxifene Acetate Tablets

**Trade Name:** VIVIANT; CONBRIZA

**Chemical Family:** Not determined

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

**Intended Use:** Pharmaceutical product used for osteoporosis

### 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

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Ramsgate Road  
Sandwich, Kent  
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+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

Skin Sensitization: Category 1

Reproductive Toxicity: Category 2

#### EU Classification:

EU Indication of danger: Toxic to Reproduction: Category 3  
Irritant

EU Risk Phrases:

R62 - Possible risk of impaired fertility.

R43 - May cause sensitization by skin contact.

### Label Elements

**Signal Word:** Warning

**Hazard Statements:** H361f - Suspected of damaging fertility  
H317 - May cause an allergic skin reaction

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**Precautionary Statements:**

P302+ P352 - IF ON SKIN: Wash with plenty of soap and water  
 P363 - Wash contaminated clothing before reuse  
 P201 - Obtain special instructions before use  
 P202 - Do not handle until all safety precautions have been read and understood  
 P281 - Use personal protective equipment as required  
 P308 + P313 - IF exposed or concerned: Get medical attention/advice  
 P405 - Store locked up  
 P501 - Dispose of contents/container in accordance with all local and national regulations  
 P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention



**Other Hazards**

**Australian Hazard Classification (NOHSC):**

Hazardous Substance. Non-Dangerous Goods.

**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

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Bazedoxifene Acetate	198481-33-3	Not Listed	N;R50/53 Repr Cat.3;R62 Xi,R43	Aquatic Acute 1;H400 Aquatic Chronic 1;H410 Repr.2;H361f Skin Sens. 1,H317	5-10
Silica colloidal, Ph. Eur.	112945-52-5	Not Listed	Not Listed	Not Listed	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	*
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sodium starch glycolate	9063-38-1	Not Listed	Not Listed	Not Listed	*
Ascorbic acid (Vitamin C)	50-81-7	200-066-2	Not Listed	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	Not Listed	*
Opadry white	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Opadry clear	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*

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**Additional Information:** 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

#### 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 CO<sub>2</sub>, 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. May include oxides of carbon and nitrogen

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

#### 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.

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### 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

#### 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.

#### Bazedoxifene Acetate

Pfizer OEL TWA-8 Hr: 1µg/m<sup>3</sup>, Sensitizer

#### Silica colloidal, Ph. Eur.

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

#### Starch, pregelatinized

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>  
Bulgaria OEL - TWA 10.0 mg/m<sup>3</sup>  
Czech Republic OEL - TWA 4.0 mg/m<sup>3</sup>  
Greece OEL - TWA 10 mg/m<sup>3</sup>  
Ireland OEL - TWAs 5 mg/m<sup>3</sup>  
10 mg/m<sup>3</sup>  
4 mg/m<sup>3</sup>  
OSHA - Final PELs - TWAs: 15 mg/m<sup>3</sup>  
Portugal OEL - TWA 10 mg/m<sup>3</sup>  
Slovakia OEL - TWA 4 mg/m<sup>3</sup>  
Spain OEL - TWA 10 mg/m<sup>3</sup>  
Switzerland OEL - TWAs 3 mg/m<sup>3</sup>

#### 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>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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>

Sodium lauryl sulfate  
Pfizer OEL TWA-8 Hr: 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>

#### 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Tablets	<b>Color:</b>	White
<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)**

**Bazedoxifene Acetate**  
Measured 7.8 Log P 4.98

**Lactose NF, monohydrate**  
No data available

**Microcrystalline cellulose**  
No data available

**Sodium starch glycolate**  
No data available

**Ascorbic acid (Vitamin C)**  
No data available

**Magnesium Stearate**

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

**Water, purified**

No data available

**Opadry clear**

No data available

**Opadry white**

No data available

**Sodium lauryl sulfate**

No data available

**Starch, pregelatinized**

No data available

**Silica colloidal, Ph. Eur.**

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:** Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and 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 information included in this section describes the potential hazards of the individual ingredients.

**Known Clinical Effects:** Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: back pain, decreased red blood cell count (anemia), headache, pain, respiratory infection, bronchial tube inflammation (bronchitis), urinary tract infection, allergic reaction, hives, redness and swelling of the skin (urticaria), insomnia, depression, palpitations, hot flashes, diarrhea, difficult digestion (dyspepsia), constipation, acid reflux, dry mouth, and flatulence.

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### 11. TOXICOLOGICAL INFORMATION

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

##### **Bazedoxifene Acetate**

Rat Oral LD 50 > 4000 mg/kg  
Mouse Oral LD 50 > 4000mg/kg

##### **Microcrystalline cellulose**

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

##### **Ascorbic acid (Vitamin C)**

Rat Oral LD 50 11.9 g/kg

##### **Sodium lauryl sulfate**

Rat Oral LD50 1288 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)

##### **Bazedoxifene Acetate**

Skin Irritation Rabbit Non-irritating  
Skin Sensitization - LLNA Mouse Positive  
Eye Irritation (*In vitro*, REET) Rabbit Minimal  
Eye Irritation Rabbit Minimal

##### **Microcrystalline cellulose**

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

##### **Sodium lauryl sulfate**

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild Moderate  
Skin Sensitization - GPMT Guinea Pig Negative  
Skin Sensitization - LLNA Mouse Negative

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

##### **Bazedoxifene Acetate**

30 Day(s) Rat Oral (F) 5 mg/kg/day LOAEL Female reproductive system  
30 Day(s) Non-human Primate Oral (M) 200 mg/kg/day NOAEL None identified  
30 Day(s) Non-human Primate Oral (F) 10 mg/kg/day LOAEL Female reproductive system  
26 Week(s) Rat Oral 10 mg/kg/day LOAEL Skin, Female reproductive system, Mammary gland, Kidney  
27 Week(s) Non-human Primate Oral 1 mg/kg/day LOAEL Female reproductive system

##### **Magnesium Stearate**

13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

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

##### **Bazedoxifene Acetate**

Reproductive & Fertility-Males Rat Oral 300 mg/kg/day NOAEL Fertility

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### 11. TOXICOLOGICAL INFORMATION

Reproductive & Fertility - Females	Rat	Oral	0.3 mg/kg/day	LOAEL	Fertility, Reproductive toxicity, Maternal Toxicity
Embryo / Fetal Development	Rabbit	Oral	0.5 mg/kg/day	LOAEL	Developmental toxicity, Maternal Toxicity
Embryo / Fetal Development	Rat	Oral	1 mg/kg/day	LOAEL	Maternal Toxicity, Fetotoxicity

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

##### **Bazedoxifene Acetate**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> Micronucleus	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vivo</i> Micronucleus	Mouse Bone Marrow	Negative
Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative

##### **Sodium lauryl sulfate**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
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#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### **Bazedoxifene Acetate**

2 Year(s)	Rat	Oral, in feed	Benign tumors
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#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

#### Silica colloidal, Ph. Eur.

IARC: Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Releases to the environment should be avoided. The Drug Product Level data below is for a substantially similar mixture.

#### **Toxicity:**

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

##### **Bazedoxifene Acetate**

<i>Selenastrum capricornutum</i> (Green Alga)	OECD	EC50	72 Hours	0.46 mg/L
<i>Pseudokirchneriella subcapitata</i> (Green Alga)	OECD	ErC50	72 Hours	0.095 mg/L
<i>Pimephales promelas</i> (Fathead Minnow)	OECD	LC50	96 Hours	1.77 mg/L
<i>Daphnia magna</i> (Water Flea)	OECD	LC50	48 Hours	6.28 mg/L

##### **Sodium lauryl sulfate**

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LC50	96 Hours	3.6 mg/L
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#### Bacterial Inhibition: (Inoculum, Method, End Point, Result)

##### **Bazedoxifene Acetate**

Activated sludge	OECD	EC50	> 8.0 mg/L
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#### Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

##### **Bazedoxifene Acetate**



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*Pimephales promelas* (Fathead Minnow) OECD 33 Day(s) NOEC 0.86 mg/L Survival  
*Daphnia magna* (Water Flea) OECD 21 Day(s) NOEC 1.1 mg/L Reproduction  
*Daphnia magna* (Water Flea) OECD 21 Day(s) EC50 1.8 mg/L Survival  
*Chironomus riparius* (Midges) OECD 28 Day(s) NOEC 85 mg/kg Growth

### Persistence and Degradability:

**Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)**

#### Bazedoxifene Acetate

OECD Activated sludge 0% After 28 Day(s) Not Ready

### Bio-accumulative Potential:

**Partition Coefficient: (Method, pH, Endpoint, Value)**

#### Bazedoxifene Acetate

Measured 7.8 Log P 4.98

**Mobility in Soil:** No data available

### Data for the Drug Product

#### Aquatic Toxicity

Species	Method	End Point	Duration	Result (mg/l)
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	OECD	LC50	96 Hours	>100
<i>Daphnia Magna</i> (Water Flea)	ISO	EC50	48 Hours	>100
<i>Pseudokirchneriella subcapitata</i> (Green Alga)	ISO	IC50	72 Hours	>100

## 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**

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**15. REGULATORY INFORMATION**

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**  
 D2a very toxic materials  
 D2b toxic materials



**Bazedoxifene Acetate**

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

**Silica colloidal, Ph. Eur.**

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

**Sodium starch glycolate**

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

**Starch, pregelatinized**

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 IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

**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

**Ascorbic acid (Vitamin C)**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

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REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-066-2
<b>Sodium lauryl sulfate</b>	
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 6
EU EINECS/ELINCS List	205-788-1
<b>Lactose NF, monohydrate</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	Not Listed
<b>Water, purified</b>	
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 IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
<b>Magnesium Stearate</b>	
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
<b>Opadry white</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
<b>Opadry clear</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

### 16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

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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  
Reproductive toxicity-Cat.2; H361f - Suspected of damaging fertility  
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

N - Dangerous for the environment  
Toxic to Reproduction: Category 3  
Xi - Irritant

R62 - Possible risk of impaired fertility.  
R43 - May cause sensitization by skin contact.  
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.

**Reasons for Revision:** Updated Section 14 - Transport Information. Updated Section 2 - Hazard Identification.  
Updated Section 12 - Ecological Information.

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**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**