



SAFETY DATA SHEET

Revision date: 02-Nov-2017

Version: 3.0

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

Product Identifier

Material Name: Bazedoxifene - Conjugated Estrogen Tablets

Trade Name: DUAVEE; DUAVIVE; APRELA
Synonyms: Bazedoxifene, Conjugated Estrogen Tablets
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

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

Skin Sensitization: Category 1
Reproductive Toxicity: Category 1A
Carcinogenicity: Category 1A

Label Elements

Signal Word: Warning
Hazard Statements: H317 - May cause an allergic skin reaction
H350 - May cause cancer
H360FD - May damage fertility. May damage the unborn child.

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Precautionary Statements:

- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P363 - Wash contaminated clothing before reuse
- P272 - Contaminated work clothing must not be allowed out of the workplace
- P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
- P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
- P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P321 - Specific treatment (see supplemental first aid instructions on this label)
- P405 - Store locked up
- 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 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	%
Bazedoxifene Acetate	198481-33-3	Not Listed	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Repr.2 (H361f) Skin Sens. 1 (H317)	5-10
Conjugated estrogens	12126-59-9	235-199-5	Carc.1A (H350) Repr.1A (H360FD)	0.2
Ferric oxide red	1309-37-1	215-168-2	Not Listed	*
Isopropyl alcohol	67-63-0	200-661-7	STOT SE 3 (H336) Flam. Liq. 2 (H225) Eye Irrit. 2A (H319)	<1.0
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Sucrose	57-50-1	200-334-9	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	<0.1

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Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Ascorbic acid (Vitamin C)	50-81-7	200-066-2	Not Listed	*
Black Iron Oxide	1317-61-9	215-277-5	Not Listed	*
Calcium phosphate, tribasic	7758-87-4	231-840-8	Not Listed	*
Ferric oxide yellow	51274-00-1	257-098-5	Not Listed	*
Hydroxyethyl cellulose	9004-62-0	Not Listed	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*
Maltitol	585-88-6	209-567-0	Not Listed	*
Poloxalene	9003-11-6	Not Listed	Not Listed	*
Polydextrose	68424-04-4	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*
Sucrose Palmitate	26446-38-8	247-706-7	Not Listed	*

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. * Proprietary
 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. May include oxides of carbon and nitrogen
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

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Advice for Fire-Fighters

During all firefighting 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. Cleanup 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. 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/m³, Sensitizer

Conjugated estrogens

Pfizer OEL TWA-8 Hr: 0.15µg/m³

Ferric oxide red

ACGIH Threshold Limit Value (TWA) 5 mg/m³

Australia TWA 5 mg/m³
10 mg/m³

Austria OEL - MAKs 5 mg/m³
10 mg/m³

Belgium OEL - TWA 5 mg/m³

Bulgaria OEL - TWA 5.0 mg/m³

Denmark OEL - TWA 3.5 mg/m³

Estonia OEL - TWA 3.5 mg/m³

Finland OEL - TWA 5 mg/m³

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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
Sweden OEL - TWAs	3.5 mg/m ³
Switzerland OEL - TWAs	3 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³
Isopropyl alcohol	
ACGIH Threshold Limit Value (TWA)	200 ppm
ACGIH Threshold Limit Value (STEL)	400 ppm
ACGIH - Biological Exposure Limit:	40 mg/L
Australia STEL	500 ppm
	1230 mg/m ³
Australia TWA	400 ppm
	983 mg/m ³
Austria OEL - MAKs	200 ppm
	500 mg/m ³
Belgium OEL - TWA	200 ppm
	500 mg/m ³
Bulgaria OEL - TWA	980.0 mg/m ³
Czech Republic OEL - TWA	500 mg/m ³
Denmark OEL - TWA	200 ppm
	490 mg/m ³
Estonia OEL - TWA	150 ppm
	350 mg/m ³
Finland OEL - TWA	200 ppm
	500 mg/m ³
Germany - TRGS 900 - TWAs	200 ppm
	500 mg/m ³
Germany (DFG) - MAK	200 ppm
	500 mg/m ³
Germany - Biological Exposure Limit:	25 mg/L
Greece OEL - TWA	400 ppm
	980 mg/m ³
Hungary OEL - TWA	500 mg/m ³
Ireland OEL - TWAs	200 ppm
Japan - OELs - Ceilings	400 ppm
	980 mg/m ³
Latvia OEL - TWA	350 mg/m ³
Lithuania OEL - TWA	150 ppm
	350 mg/m ³

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OSHA - Final PELS - TWAs:	400 ppm 980 mg/m ³
Poland OEL - TWA	900 mg/m ³
Portugal OEL - TWA	200 ppm
Romania OEL - TWA	81 ppm 200 mg/m ³
Romania - Biological Exposure Limit:	50 mg/L
Russia OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	200 ppm 500 mg/m ³
Slovenia OEL - TWA	200 ppm 500 mg/m ³
Spain OEL - TWA	200 ppm 500 mg/m ³
Spain - Biological Exposure Limit:	40 mg/L
Sweden OEL - TWAs	150 ppm 350 mg/m ³
Switzerland OEL -TWAs	200 ppm 500 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
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
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
Propylene glycol	

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Australia TWA	150 ppm
	474 mg/m ³
	10 mg/m ³
Ireland OEL - TWAs	150 ppm
	470 mg/m ³
	10 mg/m ³
Latvia OEL - TWA	7 mg/m ³
Lithuania OEL - TWA	7 mg/m ³
Sucrose	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 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
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
Ascorbic acid (Vitamin C)	
Pfizer Occupational Exposure Band (OEB):	OEB 1 (control exposure to the range of 1000ug/m ³ to 3000ug/m ³)

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 disposable gloves (e.g. Nitrile, etc.) (double 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 disposable 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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:

Tablets

Color:

Brown or Pink

Odor:

No data available.

Odor Threshold:

No data available.

Molecular Formula:

Mixture

Molecular Weight:

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

Ascorbic acid (Vitamin C)

No data available

Magnesium Stearate

No data available

Conjugated estrogens

No data available

Hydroxypropyl cellulose

No data available

Calcium phosphate, tribasic

No data available

Hydroxyethyl cellulose

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9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Sucrose Palmitate

No data available

Sucrose

No data available

Polyethylene glycol

No data available

Black Iron Oxide

No data available

Hydroxypropyl methylcellulose

No data available

Isopropyl alcohol

No data available

Maltitol

No data available

Poloxalene

No data available

Polydextrose

No data available

Povidone

No data available

Ferric oxide red

No data available

Titanium dioxide

No data available

Ferric oxide yellow

No data available

Propylene glycol

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.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

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10. STABILITY AND REACTIVITY

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.

Long Term:

Repeat-dose studies in animals have shown a potential to cause adverse effects on fertility, reproductive system, and the developing fetus. Occupational studies have shown that males working with estrogen-like compounds have shown clinical signs of hyperestrogenism including enlarged breasts and milk secretion. Loss of libido, breast tenderness, and changes in sex hormone levels have also occurred. Occupational exposure in females has resulted in menstrual irregularities (breakthrough bleeding, menstrual flow changes, spotting and amenorrhea).

Known Clinical Effects:

Clinical use of estrogens has resulted in breast changes (enlargement, tenderness, and secretion), along with effects on the genitourinary (changes in vaginal bleeding), and GI systems. Effects on the skin, eyes, and CNS have also been reported. Ingestion of this material may cause effects similar to those seen in clinical use including 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.

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

Conjugated estrogens

Rat IP LD50 325 mg/kg
Mouse IV LD50 1740mg/kg
Rat Oral LD50 > 5000mg/kg

Sucrose

Rat Oral LD50 29.7 g/kg

Black Iron Oxide

Rat Oral LD50 >1000 mg/kg

Hydroxypropyl methylcellulose

Rat Oral LD50 > 10,000 mg/kg

Isopropyl alcohol

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Rat Oral LD50 > 2000 mg/kg
Mouse Oral LD50 3600 mg/kg
Rat Inhalation LC50-8h 16,000 ppm
Rabbit Dermal LD50 12800 mg/kg
Rat Inhalation LC50 30mg/L

Titanium dioxide

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

Propylene glycol

Rat Oral LD 50 22,000 mg/kg
Mouse Oral LD 50 24,900mg/kg
Rabbit Dermal LD 50 20,800mg/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

Conjugated estrogens

Eye Irritation Rabbit Severe

Polyethylene glycol

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Isopropyl alcohol

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

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

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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
9 Month(s)	Non-human Primate	Oral	300 mg/kg/day	NOAEL	Female reproductive system

Magnesium Stearate

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

20 Week(s)	Rat	Inhalation	4000 ppm	NOAEL	Liver, Central nervous system
104 Week(s)	Rat	Inhalation	5000 ppm		Kidney

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
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

Conjugated estrogens

Embryo / Fetal Development	Rat	Subcutaneous	7 mg/kg/day	LOAEL	Embryotoxicity, Fetotoxicity
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Isopropyl alcohol

Prenatal & Postnatal Development	Rat	Inhalation	7,000 ppm	LOAEL	Maternal toxicity, Fetotoxicity, Embryotoxicity
2 Generation Reproductive Toxicity	Rat	Oral	1000 mg/kg/day	LOAEL	Maternal Toxicity, Fetal mortality
Prenatal & Postnatal Development	Rat	Oral	1200 mg/kg/day	NOAEL	No effects at maximum dose,

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

Sucrose

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
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Isopropyl alcohol

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Mammalian Cell Mutagenicity	HGPRT Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Sister Chromatid Exchange		Negative

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

Bazedoxifene Acetate

2 Year(s)	Rat	Oral, in feed		Benign tumors
26 Week(s)	Mouse	Oral	>= 150 mg/kg/day	Benign tumors

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11. TOXICOLOGICAL INFORMATION

Carcinogen Status:	See below
Conjugated estrogens	
IARC:	Group 1
NTP:	Listed
Isopropyl alcohol	
IARC:	Group 3 (Not Classifiable)
Povidone	
IARC:	Group 3 (Not Classifiable)
Ferric oxide red	
IARC:	Group 3 (Not Classifiable)
Titanium dioxide	
IARC:	Group 2B (Possibly Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

Environmental Overview: The following information is available for the individual ingredients. See below for data on the drug product.

Toxicity:

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

Bazedoxifene Acetate

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

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

Bazedoxifene Acetate

Activated sludge OECD EC50 > 8.0 mg/L

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

Bazedoxifene Acetate

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:

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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 mg/L
<i>Daphnia Magna</i> (Water Flea)	ISO	EC50	48 Hours	>100 mg/L
<i>Pseudokirchneriella subcapitata</i> (Green Alga)	ISO	IC50	72 Hours	>100 mg/L

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

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

Ascorbic acid (Vitamin C)

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

Inventory - United States TSCA - Sect. 8(b)

Present

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15. REGULATORY INFORMATION

Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-066-2
Bazedoxifene Acetate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Black 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	215-277-5
Calcium phosphate, tribasic	
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	231-840-8
Conjugated estrogens	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen, initial date 2/27/87; developmental. initial date 4/1/90
EU EINECS/ELINCS List	235-199-5
Ferric oxide red	
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
Ferric oxide yellow	
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	257-098-5
Hydroxyethyl 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	Not Listed
Hydroxypropyl cellulose	
CERCLA/SARA 313 Emission reporting	Not Listed

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California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Hydroxypropyl methylcellulose	
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
Isopropyl alcohol	
CERCLA/SARA 313 Emission reporting	1.0 %
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-661-7
Lactose NF, monohydrate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
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
Maltitol	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
EU EINECS/ELINCS List	209-567-0
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
Poloxalene	
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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EU EINECS/ELINCS List	Not Listed
Polydextrose	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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
Povidone	
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
Propylene glycol	
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	200-338-0
Sucrose	
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	200-334-9
Sucrose Palmitate	
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	247-706-7
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

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15. REGULATORY INFORMATION

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

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
Reproductive toxicity-Cat.1A; H360FD - May damage fertility. May damage the unborn child.
Carcinogenicity-Cat.1A; H350 - May cause cancer
Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; H336 - May cause drowsiness and dizziness
Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 02-Nov-2017
Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet