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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

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

EU Classification:

EU Indication of danger: Carcinogenic: Category 1
Irritant
Toxic to reproduction: Category 1

EU Risk Phrases:

R43 - May cause sensitization by skin contact.
R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

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.
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 should not be allowed out of the workplace
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P302+P313 - If skin irritation or rash occurs: Get medical advice/attention
P308+P313 - If exposed or concerned: Get medical advice/attention
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

Australian Hazard Classification (NOHSC):


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

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bazedoxifene Acetate</td>
<td>198481-33-3</td>
<td>Not Listed</td>
<td>N;R50/53</td>
<td>Aquatic Acute 1;H400</td>
<td>5-10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr. Cat.3;R62</td>
<td>Aquatic Chronic 1;H410</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Xi,R43</td>
<td>Repr.2;H361f</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Sens. 1;H317</td>
<td></td>
</tr>
<tr>
<td>Polylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Conjugated estrogens</td>
<td>12126-59-9</td>
<td>235-199-5</td>
<td>Carc. Cat.1;R45</td>
<td>Carc. 1A,H350;</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr. Cat.1;R60</td>
<td>Repr. 1A,H360FD</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr. Cat.1;R61</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical ink</td>
<td>Not assigned</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

WR00122
**SAFETY DATA SHEET**

Material Name: Bazedoxifene/Conjugated Estrogen Tablets

Revision date: 20-Oct-2014

---

### 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.

**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.

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

Polyethylene glycol
Austria OEL - MAKs 1000 mg/m³
Germany - TRGS 900 - TWAs 1000 mg/m³
Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600
Slovakia OEL - TWA 1000 mg/m³
Slovenia OEL - TWA 1000 mg/m³
Switzerland OEL -TWAs 1000 ppm

Sucrose
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 10 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 6 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure 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:**

- **Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
- **Eyes:** Wear safety glasses or goggles if eye contact is possible.
- **Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
- **Respiratory protection:** If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** 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
9. PHYSICAL AND CHEMICAL PROPERTIES

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
Water, purified
No data available
Conjugated estrogens
No data available
Hydroxypropyl cellulose
No data available
Calcium phosphate, tribasic
No data available
Hydroxyethyl cellulose
No data available
Sucrose Palmitate
No data available
Sucrose
No data available
Polyethylene glycol
No data available
Tablet coating
No data available
Pharmaceutical ink
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
10. STABILITY AND REACTIVITY

| 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       |
| 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 LD50 > 4000 mg/kg
- Mouse Oral LD50 > 4000mg/kg

**Microcrystalline cellulose**

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

**Ascorbic acid (Vitamin C)**

- Rat Oral LD50 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

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
11. TOXICOLOGICAL INFORMATION

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

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
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

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

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

Sucrose
Bacterial Mutagenicity (Ames)  Salmonella  Negative

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

Bazedoxifene Acetate
2 Year(s)  Rat  Oral, in feed  Benign tumors
SAFETY DATA SHEET

11. TOXICOLOGICAL INFORMATION

Carcinogen Status: See below

Conjugated estrogens
IARC: Group 1
NTP: Listed

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:
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

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result (mg/l)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selenastrum capricornutum (Green Alga)</td>
<td>OECD</td>
<td>EC50</td>
<td>72 Hours</td>
<td>0.46 mg/L</td>
</tr>
<tr>
<td>Pseudokirchneriella subcapitata (Green Alga)</td>
<td>OECD</td>
<td>ErC50</td>
<td>72 Hours</td>
<td>0.095 mg/L</td>
</tr>
<tr>
<td>Pimephales promelas (Fathead Minnow)</td>
<td>OECD</td>
<td>LC50</td>
<td>96 Hours</td>
<td>1.77 mg/L</td>
</tr>
<tr>
<td>Daphnia magna (Water Flea)</td>
<td>OECD</td>
<td>LC50</td>
<td>48 Hours</td>
<td>6.28 mg/L</td>
</tr>
</tbody>
</table>

Material Name: Bazedoxifene/Conjugated Estrogen Tablets
Revision date: 20-Oct-2014
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

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

Polyethylene glycol
CERCLA/SARA 313 Emission reporting  Not Listed
### 15. REGULATORY INFORMATION

**Material Name:** Bazedoxifene/Conjugated Estrogen Tablets  
**Revision date:** 20-Oct-2014  
**Version:** 2.0  
**Page:** 11 of 13

<table>
<thead>
<tr>
<th>Material</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>REACH - Annex IV - Exemptions from the obligations of Register:</th>
<th>EU EINECS/ELINCS List</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose NF, monohydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
<td>Schedule 3</td>
</tr>
<tr>
<td>Sucrose</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Present</td>
<td>200-334-9</td>
<td></td>
</tr>
<tr>
<td>Water, purified</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Hydroxypropyl cellulose</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Present</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Present</td>
<td>209-150-3</td>
<td></td>
</tr>
<tr>
<td>Calcium phosphate, tribasic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcrystalline cellulose</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>231-840-8</td>
</tr>
<tr>
<td>Ascorbic acid (Vitamin C)</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>200-066-2</td>
</tr>
<tr>
<td>Sucrose Palmitate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>247-706-7</td>
</tr>
<tr>
<td>Tablet coating</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conjugated estrogens</td>
<td>Not Listed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

REACH - Annex IV - Exemptions from the obligations of Register:

Microcrystalline cellulose

Use restricted. See item 9[f]. powder

16. OTHER INFORMATION

Text of R phrases and 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

N - Dangerous for the environment
Toxic to Reproduction: Category 3
Xi - Irritant
Toxic to reproduction: Category 1
Carcinogenic: Category 1

R62 - Possible risk of impaired fertility.
R43 - May cause sensitization by skin contact.
R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R52/53 - Harmful 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 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 12 - Ecological Information. Updated Section 14 - Transport Information. Updated Section 16 - Other Information.

Revision date: 20-Oct-2014
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