SAFETY DATA SHEET

1. Identification

Product identifier  Evista®

Other means of identification

Item Code  
VF0366, UC4810, TA4166, VF0338, VF0316, TA4466, TA4165, TA4164, VF0317, VF0297, VF0298, TA4012, ND1002, TA4013, VF0374, SA1006, BO2059, UC4165, ZD4165

Synonyms  Methanone, [6-hydroxy-2-(4-hydroxyphenyl)benzo[b]thien-3-yl][4-[2-(1-piperidinyl)ethoxy]phenyl]-,hydrochloride

Recommended use  Pharmaceutical

Recommended restrictions  None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name  Eli Lilly and Company
Address  Lilly Corporate Center
Indianapolis, IN 46285
United States

Telephone  Phone: +1-317-276-2000
E-mail  lilly_msds@lilly.com
Emergency phone number  CHEMTREC: +1-800-424-9300

LY Number  LY139481 Hydrochloride
LSN Number  156758

2. Hazard(s) identification

Physical hazards  Not classified.

Health hazards  Carcinogenicity  Category 2
Reproductive toxicity  Category 1A

OSHA defined hazards  Not classified.

Label elements

Signal word  Danger

Hazard statement

H351  Suspected of causing cancer.
H360  May damage fertility or the unborn child.

Precautionary statement

Prevention

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.

Response

P308 + P313  IF exposed or concerned: Get medical advice/attention.

Storage  Not available.
Disposal  Not available.

Hazard(s) not otherwise classified (HNOC)  None known.

Supplemental information  None.
3. Composition/information on ingredients

**Mixtures**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raloxifene Hydrochloride</td>
<td>[6-hydroxy-2-(4-hydroxyphenyl)-1-benzothiophen-3-yl][4-(2-piperidin-1-ylethoxy)phenyl]methanone hydrochloride</td>
<td>82640-04-8</td>
<td>10 - 65</td>
</tr>
<tr>
<td></td>
<td>Methanone, [6-hydroxy-2-(4-hydroxyphenyl)benzo[b]thien-3-yl][4-[2-(1-piperidinyl)ethoxy]phenyl]-, hydrochloride</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Benzothiophene</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Composition comments**

Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

4. First-aid measures

**Inhalation**

Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.

**Skin contact**

Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists.

**Eye contact**

In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.

**Ingestion**

Immediately give large quantities of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician immediately.

**Most important symptoms/effects, acute and delayed**

Exposure to raloxifene hydrochloride resulted in skin rash/redness. Raloxifene hydrochloride is a Selective Estrogen Receptor Modulator (SERM) and is highly potent. Reproductive effects in females and developmental effects are associated with compounds in this pharmacological class, including raloxifene hydrochloride.

**General information**

Capsules or tablets are not considered hazardous under normal handling procedures. Capsules and tablets are intended for human consumption under guidance of a physician.

5. Fire-fighting measures

**Suitable extinguishing media**

Carbon dioxide, dry chemical or water.

**Unsuitable extinguishing media**

None known.

**Specific hazards arising from the chemical**

During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion. Chloride.

**Special protective equipment and precautions for firefighters**

Wear self-contained breathing apparatus and protective clothing.

6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**

Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment.

**Methods and materials for containment and cleaning up**

Do not sweep. Collect spill using a vacuum cleaner with a HEPA filter. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping.

**Environmental precautions**

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

**Precautions for safe handling**

Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. See Section 8 of the SDS for Personal Protective Equipment.

**Conditions for safe storage, including any incompatibilities**

Keep container tightly closed in a dry and well-ventilated place.

8. Exposure controls/personal protection

**Occupational exposure limits**

<table>
<thead>
<tr>
<th>Material name: Evista®</th>
<th>5000</th>
<th>Version #: 03</th>
<th>Revision date: 09-23-2015</th>
<th>Issue date: 12-08-2014</th>
<th>SDS US</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lilly (LEG) Components</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 / 8</td>
</tr>
<tr>
<td>Raloxifene Hydrochloride (CAS 82640-04-8)</td>
<td>Excursion Limit</td>
<td>130 ug/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>TWA (12hrs)</td>
<td>5 ug/m³</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, isolator (i.e. glove bag/glove box) and/or closed transfers to maintain airborne levels below occupational exposure level (OEL).

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Safety glasses with side shields recommended. If splash potential or dusty operations, wear goggles/faceshield.

#### Skin protection

- Hand protection: Chemical resistant gloves.
- Other: Chemical-resistant gloves and impermeable body covering to minimize skin contact.

#### Respiratory protection

If the applicable occupational exposure level (OEL) is anticipated to be exceeded, wear an approved respirator with sufficient protection factor to control exposure below the OEL. If material is handled in a fume hood or ventilated enclosure, consider using redundant respiratory protection.

#### Thermal hazards

Not available.

### General hygiene considerations

Engineering controls should be used as the primary means to control workplace exposures. Follow good workplace hygiene practices such as washing hands after handling this material. Raloxifene Hydrochloride is an active pharmaceutical ingredient with a therapeutic dose in humans at or below 1 mg/day.

### 9. Physical and chemical properties

#### Appearance

- **Physical state**: Solid.
- **Form**: Tablet.
- **Color**: Light yellow
- **Odor**: Odorless

#### Odor threshold

No data available.

#### pH

No data available.

#### Melting point/freezing point

No data available.

#### Initial boiling point and boiling range

No data available.

#### Flash point

Not applicable.

#### Evaporation rate

No data available.

#### Flammability (solid, gas)

No test data available.

#### Upper/lower flammability or explosive limits

- **Flammability limit - lower (%)**: No data available.
- **Flammability limit - upper (%)**: No data available.
- **Explosive limit - lower (%)**: No data available.
- **Explosive limit - upper (%)**: No data available.

#### Vapor pressure

No data available.

#### Vapor density

No data available.

#### Relative density

No data available.

#### Solubility(ies)

- **Solubility (water)**: Insoluble

#### Partition coefficient (n-octanol/water)

No data available.

#### Auto-ignition temperature

No data available.
Decomposition temperature: No data available.
Viscosity: No data available.

Other information:
- Density: No data available.
- Explosive properties: Not explosive.
- Oxidizing properties: The substance or mixture is not classified as oxidizing.
- Percent volatile: No data available.
- VOC (Weight %): No data available.

10. Stability and reactivity

Reactivity: Not water reactive.
Chemical stability: Material is stable under normal conditions.
Possibility of hazardous reactions: Hazardous polymerization does not occur.
Conditions to avoid: None known.
Incompatible materials: Strong oxidizing substances.

Hazardous decomposition products: During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion. Chloride.

11. Toxicological information

Information on toxicological effects

Acute toxicity: Based on available data, the classification criteria are not met.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raloxifene Hydrochloride (CAS 82640-04-8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>Rabbit</td>
<td>&gt; 200 mg/kg</td>
</tr>
<tr>
<td>LD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation</td>
<td>Monkey</td>
<td>&gt; 27 mg/m3, 8 hr</td>
</tr>
<tr>
<td>LC50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td>LD</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Skin corrosion/irritation: Rabbit: Slight irritation. (Raloxifene hydrochloride)
Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation: Rabbit: Slight irritation. (Raloxifene hydrochloride)
Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

Respiratory sensitization: Due to lack of data the classification is not possible.

Skin sensitization: Did not cause sensitization on laboratory animals. (Raloxifene hydrochloride)
Based on available data, the classification criteria are not met.

Germ cell mutagenicity: In vitro and in vivo tests did not show mutagenic effects. (Raloxifene hydrochloride)
Based on available data, the classification criteria are not met.

Carcinogenicity: Suspected of causing cancer. Increased incidences of ovarian, testicular, and prostatic tumors were reported in long-term studies in rodents. These effects were attributed to dose-dependent hormonal pharmacology. (Raloxifene hydrochloride)

IARC Monographs. Overall Evaluation of Carcinogenicity
Not available.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens
Not available.
Reproductive toxicity

No pregnancies occurred when male and female rats were given daily doses of 5 mg/kg prior to and during mating. In female rats, disrupted estrous cycles and inhibited ovulation (all reversible), and delayed and disrupted embryo implantation resulting in prolonged gestation and reduced litter size were reported. Developmental effects reported included decreased fetal weight and delayed skeletal development, growth retardation, malformations of the heart, edema, and hydrocephaly in offspring. In male rats, daily doses up to 100 mg/kg for at least 2 weeks did not affect sperm production/quality or reproductive performance. Decreased prostate weights and a single case of aspermatogenesis were observed in dogs given 30 mg/kg for 6-months. No significant observations in sperm count/motility and morphology were observed in humans during a 3-month clinical trial when given daily doses of 120 mg. (Raloxifene hydrochloride)

Specific target organ toxicity - single exposure

Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure

No significant target organ toxicity reported. (Raloxifene hydrochloride)

Aspiration hazard

No aspiration toxicity classification

Further information

Exposure to raloxifene hydrochloride resulted in skin rash/redness. Raloxifene hydrochloride is a Selective Estrogen Receptor Modulator (SERM) and is highly potent. Reproductive effects in females and developmental effects are associated with compounds in this pharmacological class, including raloxifene hydrochloride.

12. Ecological information

Ecotoxicity

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raloxifene Hydrochloride (CAS 82640-04-8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IC50</td>
<td></td>
<td>&gt; 1000 mg/l (Bacteria, n-fixing)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 1000 mg/l (Fungus)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 1000 mg/l (Mold)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 1000 mg/l (Bacteria, soil)</td>
</tr>
<tr>
<td>Other</td>
<td>EC50</td>
<td>Selenastrum capricornutum (new name Pseudokirchnerella subca)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.21 mg/l (average specific growth rate)</td>
</tr>
<tr>
<td>Aquatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Algae</td>
<td>IC50</td>
<td>Blue-green algae (Spirulina platensis)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>875 mg/l</td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>Daphnia magna</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.43 mg/l</td>
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<tr>
<td>NOEC</td>
<td></td>
<td>Daphnia magna</td>
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<tr>
<td></td>
<td></td>
<td>0.165 mg/l</td>
</tr>
<tr>
<td>Fish</td>
<td>LC50</td>
<td>Oncorhynchus mykiss</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.45 mg/l, 96 hr</td>
</tr>
</tbody>
</table>

Persistence and degradability

Hydrolysis half-life (days): 1001, 410, 90 (pH 5, 7, 9)
Sewage sludge degradation half-life (0.47 g/L total suspended solids): 7.17 hours
Aerobic biodegradation half-life (0.03 g/L total suspended solids): 37 days

Bioaccumulative potential

log Kow: < 4.

Partition coefficient n-octanol / water (log Kow)

Raloxifene Hydrochloride

| pH 5  | 2.71 |
|------------------|
| pH 7  | 3.12 |
| pH 9  | 3.19 |

Mobility in soil

No data available.

Other adverse effects

Not available.

Ecotoxicological Properties

Drinking Water

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raloxifene Hydrochloride</td>
<td>3.5 µg/l</td>
</tr>
</tbody>
</table>

Chronic Exposure of Aquatic Organisms

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raloxifene Hydrochloride</td>
<td>0.01 µg/l</td>
</tr>
</tbody>
</table>
13. Disposal considerations

Disposal instructions: Dispose of contents/container in accordance with local/regional/national/international regulations.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN3077</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name</td>
<td>Environmentally hazardous substances, solid, n.o.s. (Raloxifene Hydrochloride)</td>
</tr>
</tbody>
</table>

- Transport hazard class(es)
  - Class: 9
  - Subsidiary risk: -
  - Packing group: III
  - Environmental hazards: Yes
  - ERG Code: 9L
  - Special precautions for user: Not available.
  - Other information:
    - Passenger and cargo aircraft: Allowed.
    - Cargo aircraft only: Allowed.

IMDG

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN3077</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name</td>
<td>Environmentally hazardous substances, solid, n.o.s. (Raloxifene Hydrochloride)</td>
</tr>
</tbody>
</table>

- Transport hazard class(es)
  - Class: 9
  - Subsidiary risk: -
  - Packing group: III
  - Environmental hazards
    - Marine pollutant: Yes
    - EmS: F-A, S-F
  - Special precautions for user: Not available.
  - Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not available.

IATA; IMDG

Marine pollutant
15. Regulatory information

**US federal regulations**
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
One or more components are not listed on TSCA.

CERCLA/SARA Hazardous Substances - Not applicable.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
- Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
- Not listed.

SARA 304 Emergency release notification
- Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
- Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
- Immediate Hazard - No
- Delayed Hazard - Yes
- Fire Hazard - No
- Pressure Hazard - No
- Reactivity Hazard - No

**US state regulations**
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**Other federal regulations**
Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
- Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
- Not regulated.

Safe Drinking Water Act (SDWA)
- Not regulated.

**International Inventories**

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
*A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

<table>
<thead>
<tr>
<th>Issue date</th>
<th>12-08-2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date</td>
<td>09-23-2015</td>
</tr>
<tr>
<td>Version #</td>
<td>03</td>
</tr>
</tbody>
</table>
Lilly Lab Code
Health: 2
Fire: 1
Reactivity: 0
Special 1: P
Special 2: R
Special 3: sC

List of abbreviations
LEG: Lilly Exposure Guideline
TWA: Time Weighted Average

Disclaimer
As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
Eli Lilly and Company
Hazard Communication
+1-317-651-9533

Revision Information
Product and Company Identification: Product Codes
Hazards Identification: EU Hazard Classifications
Composition/information on ingredients: Component information
Exposure controls/personal protection: Appropriate engineering controls
Exposure controls/personal protection: General hygiene considerations
Exposure controls/personal protection: Eye/face protection
Exposure controls/personal protection: Hand protection
Exposure controls/personal protection: Respiratory protection
Regulatory Information: Risk Phrases - Class.
GHS: Classification