



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Evista®</b>	
<b>Other means of identification</b>		
<b>Item Code</b>	VF0366, UC4810, TA4166, VF0338, VF0316, TA4466, TA4165, TA4164, VF0317, VF0297, VF0298, TA4012, ND1002, TA4013, VF0374, SA1006, BO2059, UC4165, ZD4165	
<b>Synonyms</b>	LY139481 Hydrochloride * Methanone, [6-hydroxy-2-(4-hydroxyphenyl)benzo[b]thien-3-yl[4-[2-(1-piperidinyl)ethoxy]phenyl]-,hydrochloride	
<b>LY Number</b>	LY139481	
<b>Recommended use</b>	Pharmaceutical	
<b>Recommended restrictions</b>	None known.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Manufacturer</b>		
<b>Company name</b>	Eli Lilly and Company	
<b>Address</b>	Lilly Corporate Center Indianapolis, IN 46285 United States	
<b>Telephone</b>	Phone:	+1-317-276-2000
<b>E-mail</b>	lilly_msds@lilly.com	
<b>Emergency phone number</b>	CHEMTREC:	+1-800-424-9300

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Carcinogenicity	Category 2
	Reproductive toxicity	Category 1A
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger	
<b>Hazard statement</b>		
H351	Suspected of causing cancer.	
H360	May damage fertility or the unborn child.	
<b>Precautionary statement</b>		
<b>Prevention</b>		
P201	Obtain special instructions before use.	
P281	Use personal protective equipment as required.	
P202	Do not handle until all safety precautions have been read and understood.	
<b>Response</b>		
P308 + P313	IF exposed or concerned: Get medical advice/attention.	
<b>Storage</b>	Not available.	
<b>Disposal</b>	Not available.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.	
<b>Supplemental information</b>	None.	

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Raloxifene Hydrochloride	[6-hydroxy-2-(4-hydroxyphenyl)-1-benzothiophen-3-yl][4-(2-piperidin-1-yloxy)phenyl]methanone hydrochloride Methanone, [6-hydroxy-2-(4-hydroxyphenyl)benzo[b]thiophen-3-yl][4-[2-(1-piperidinyl)ethoxy]phenyl]-, hydrochloride Benzothiophene	82640-04-8	10 - 65

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

#### 4. First-aid measures

<b>Inhalation</b>	Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.
<b>Skin contact</b>	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.
<b>Eye contact</b>	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.
<b>Ingestion</b>	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.
<b>Most important symptoms/effects, acute and delayed</b>	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.
<b>General information</b>	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

<b>Suitable extinguishing media</b>	Carbon dioxide, dry chemical or water.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion. Chloride.
<b>Special protective equipment and precautions for firefighters</b>	Wear self-contained breathing apparatus and protective clothing.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment.
<b>Methods and materials for containment and cleaning up</b>	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.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

#### 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. See Section 8 of the SDS for Personal Protective Equipment.
<b>Conditions for safe storage, including any incompatibilities</b>	Keep container tightly closed in a dry and well-ventilated place.

#### 8. Exposure controls/personal protection

##### Occupational exposure limits

###### Lilly (LEG)

###### Components

Components	Type	Value
Raloxifene Hydrochloride (CAS 82640-04-8)	Excursion Limit	130 ug/m3
	TWA (12hrs)	5 ug/m3
	TWA (8hrs)	8 ug/m3

**Biological limit values** No biological exposure limits noted for the ingredient(s).

<b>Appropriate engineering controls</b>	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).
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Safety glasses with side shields recommended. If splash potential or dusty operations, wear goggles/faceshield.
<b>Skin protection</b>	
<b>Hand protection</b>	Chemical resistant gloves.
<b>Other</b>	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
<b>Respiratory protection</b>	Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator. 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.
<b>Thermal hazards</b>	Not available.
<b>General hygiene considerations</b>	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

<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Color</b>	Light yellow
<b>Odor</b>	Odorless
<b>Odor threshold</b>	No data available.
<b>pH</b>	No data available.
<b>Melting point/freezing point</b>	No data available.
<b>Initial boiling point and boiling range</b>	No data available.
<b>Flash point</b>	Not applicable.
<b>Evaporation rate</b>	No data available.
<b>Flammability (solid, gas)</b>	No test data available.

### Upper/lower flammability or explosive limits

<b>Flammability limit - lower (%)</b>	No data available.
<b>Flammability limit - upper (%)</b>	No data available.
<b>Explosive limit - lower (%)</b>	No data available.
<b>Explosive limit - upper (%)</b>	No data available.

<b>Vapor pressure</b>	No data available.
<b>Vapor density</b>	No data available.
<b>Relative density</b>	No data available.

### Solubility(ies)

<b>Solubility (water)</b>	Insoluble
<b>Partition coefficient (n-octanol/water)</b>	No data available.
<b>Auto-ignition temperature</b>	No data available.
<b>Decomposition temperature</b>	No data available.
<b>Viscosity</b>	No data available.

### Other information

<b>Density</b>	No data available.
<b>Explosive properties</b>	Not explosive.

<b>Oxidizing properties</b>	The substance or mixture is not classified as oxidizing.
<b>Percent volatile</b>	No data available.
<b>VOC</b>	No data available.

## 10. Stability and reactivity

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

Components	Species	Test Results
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Raloxifene Hydrochloride (CAS 82640-04-8)

#### Acute

##### **Dermal**

LD	Rabbit	> 200 mg/kg
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##### **Inhalation**

LC50	Monkey	> 27 mg/m <sup>3</sup> , 8 hr
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##### **Oral**

LD	Rat	> 5000 mg/kg
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**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 listed.

#### **OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

#### **US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**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.

<b>Specific target organ toxicity - repeated exposure</b>	No significant target organ toxicity reported. (Raloxifene hydrochloride) Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	No aspiration toxicity classification
<b>Further information</b>	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

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

A LAEG is the maximum allowable concentration at the point of application that is expected to result in no appreciable risk to populations of aquatic and terrestrial organisms, or to human health.

### LILLY AQUATIC EXPOSURE GUIDELINES:

#### Raloxifene Hydrochloride

Acute LAEG (at the edge of the acute mixing zone):	0.01 µg/l
Chronic LAEG (at the edge of the chronic mixing zone):	0.01 µg/l
Drinking water LAEG (at the point where surface water is taken for drinking water):	3.5 µg/l

<b>Persistence and degradability</b>	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
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**Bioaccumulative potential** log Kow: < 4.

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

Raloxifene Hydrochloride	2.71 (pH 5) 3.12 (pH 7) 3.19 (pH 9)
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**Mobility in soil** No data available.

**Other adverse effects** Not available.

## 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

<b>UN number</b>	UN3077
<b>UN proper shipping name</b>	Environmentally hazardous substances, solid, n.o.s. (Raloxifene Hydrochloride)
<b>Transport hazard class(es)</b>	
<b>Class</b>	9
<b>Subsidiary risk</b>	-

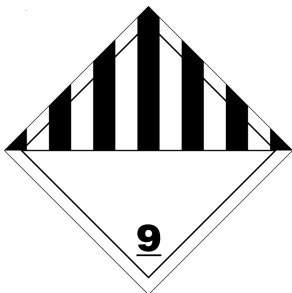
<b>Packing group</b>	III
<b>Environmental hazards</b>	Yes
<b>ERG Code</b>	9L
<b>Special precautions for user</b>	Not available.
<b>Other information</b>	
<b>Passenger and cargo aircraft</b>	Allowed with restrictions.
<b>Cargo aircraft only</b>	Allowed with restrictions.

**IMDG**

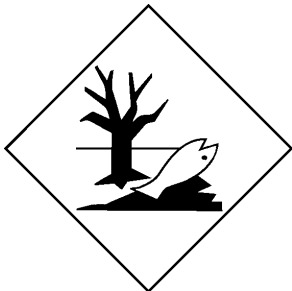
<b>UN number</b>	UN3077
<b>UN proper shipping name</b>	Environmentally hazardous substances, solid, n.o.s. (Raloxifene Hydrochloride)
<b>Transport hazard class(es)</b>	
<b>Class</b>	9
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III
<b>Environmental hazards</b>	
<b>Marine pollutant</b>	Yes
<b>EmS</b>	F-A, S-F
<b>Special precautions for user</b>	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.

**Toxic Substances Control Act (TSCA)**

**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 1910.1001-1052)**

Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

<b>Classified hazard categories</b>	Carcinogenicity Reproductive toxicity
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**SARA 313 (TRI reporting)**

Not regulated.

**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.

**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.

**International Inventories**

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*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****Issue date** 12-08-2014**Revision date** 02-27-2019**Version #** 05**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 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:

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