



# MATERIAL SAFETY DATA SHEET

**Bayer Pharmaceuticals Corporation**  
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West Haven, CT 06516-4175

**TRANSPORTATION EMERGENCY**  
CALL CHEMTREC.....: (800) 424-9300  
INTERNATIONAL.....: (703) 527-3887

**NON-TRANSPORTATION**  
BAYER EMERGENCY PHONE : (203) 812-2000  
BAYER INFORMATION PHONE: (800) 662-2927

## Section 1: Product and Company Identification

**Product Name:** LEVITRA 5MG TABL TRADE GERMANY 02720675  
**Material Number:** 8716776  
**Common/Generic Name:**  
**Chemical Name:** 2-[-2-ethoxy-5-(4-ethyl-piperazine-1-sulfonyl)-phenyl]-5-methyl-7-propyl-3H-imidazo[5,1-f]-[1,2,4]triazin-4-one monohydrochloride, trihydrate  
**Synonyms:** Levitra  
**CAS Number:** 224785-91-5

## Section 2: Composition/Information on Ingredients

### HAZARDOUS INGREDIENTS

<u>Ingredient Name/ CAS Number</u>	<u>Exposure Limits</u>	<u>Concentration</u>	
		<u>Min.</u>	<u>Max.</u>
This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.			

## Section 3: Hazards Identification

### EMERGENCY OVERVIEW

**Color:** Orange to brown **Form:** Solid Tablets **Odor:** Slight  
Product poses little or no hazard if spilled and no unusual hazard if involved in a fire. See Potential Health Effects if the recommended dosage is exceeded.

### POTENTIAL HEALTH EFFECTS

**Route(s) of Entry:** Ingestion, Skin Contact, Inhalation

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## HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE

### General Effects of Exposure

**Acute Effects of Exposure:** Acute overexposure to this product may affect color vision and cause backpain. Acute overexposure to this product may cause decreased blood pressure.

**Chronic Effects of Exposure:** Chronic overexposure to this product may cause effects as noted under acute overexposure.

### Carcinogenic Components:

**NTP:** None

**IARC:** None

**OSHA:** None

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to any components of the preparation.

**Human Health Effects Postnote:** Use only as directed. See product packaging and the Physicians' Desk Reference (PDR) for further information concerning adverse effects and drug interaction precautions. This is a pharmaceutical material.

### Section 4: First Aid Measures

**First Aid for Eye:** In case of contact, flush with plenty of water for at least 15 minutes. Contact a physician or call 203-812-2000.

**First Aid for Skin:** Contact a physician if irritation develops. In case of skin contact, wash affected areas with soap and water.

**First Aid for Inhalation:** Not applicable.

**First Aid for Ingestion:** Contact poison control center or 203-812-2000.

### Section 5: Fire Fighting Measures

**Flash Point:** Not Applicable

#### Flammable Limits:

**Upper Explosion Limit (UEL %):** Not Established

**Lower Explosion Limit (LEL %):** Not Established

**Auto-ignition Temperature:** Not Applicable

#### Extinguishing Media:

**Suitable:** Water, Foam, Dry Chemical

**Special Fire Fighting** Firefighters should be equipped with self-contained breathing

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**Procedures:** apparatus to protect against potentially toxic and irritating fumes.

#### Section 6: Accidental Release Measures

**Spill or Leak Procedures:** Spills should be swept up and placed in appropriate containers for disposal. Prevent from entering open drains and waterways. Avoid creating dusty conditions.

#### Section 7: Handling and Storage

**Storage Temperature:**  
**Maximum:** 77 °F (25 °C)

**Shelf Life:** Do not use after expiration date.

**Special Sensitivity:** Light sensitive.

**Handling/Storage Precautions:** Keep this and all drugs out of the reach of children. Avoid contact with eyes. Avoid contact with skin or clothing. Wash thoroughly after handling. Store in a dry place away from excessive heat. Containers should be kept tightly closed to prevent contamination. Use normal precautions for storage of a drug.

#### Section 8: Exposure Controls/Personal Protection

##### Personal Protection Equipment

**Eye Protection Requirements:** None for normal use.

**Skin Protection Requirements:** Lab coat., Employees should wash their hands and face before eating, drinking or using tobacco products., Gloves, long sleeved shirts and pants.

**Ventilation Requirements:** Under normal conditions of use, special ventilation is not required.

**Respirator Requirements:** A NIOSH approved dust respirator should be worn if inhalation of dust is a problem.

**Work Practices:** Normal clinical practice. Use good personal hygiene - wash hands and exposed skin thoroughly with soap and water after each use.

**Additional Protective Measures:** Employers shall provide handwashing facilities which are readily accessible to employees. Educate and train employees in the safe use and handling of this product.

#### Section 9: Physical and Chemical Properties

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**Physical Form:** Solid  
**Appearance:** Tablets  
**Color:** Orange to brown  
**Odor:** Slight  
**pH:** Not Applicable  
**Boiling Point:** Not Applicable  
**Melting/Freezing Point:** Not Applicable  
**Solubility in Water:** Hardly Soluble  
**Specific Gravity:** Not Applicable  
**Bulk Density:** Not Established  
**Vapor Pressure:** Not Applicable

#### Section 10: Stability and Reactivity

**Stability:** Stable

**Hazardous Polymerization:** Will not occur

**Substances to Avoid:** Oxidizing agents, See product packaging and the Physicians' Desk Reference (PDR) for drug interaction.

**Conditions to Avoid:** None known.

**Decomposition Products:** Carbon Dioxide, Carbon monoxide, Oxides of Nitrogen, Other potentially toxic fumes

#### Section 11: Toxicological Information

##### Toxicity Data for LEVITRA 5MG TABL TRADE GERMANY 02720675

**Toxicity Note:** See product insert for additional information concerning animal pharmacology.

**Carcinogenicity:** No carcinogenic effects observed at the doses tested.

**Mutagenicity:** Based on mutagenicity and clastogenicity screens, this product is not expected to be genotoxic.

**Developmental Toxicity/Teratogenicity:** No Teratogenic effects observed at doses tested.

**Toxicity to Reproduction/Fertility:** No effects on Reproductive parameters observed at doses tested.

#### Section 12: Ecological Information

##### Ecological Data for LEVITRA 5MG TABL TRADE GERMANY 02720675

**Ecological Note:** No data available for this product.

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**Section 13: Disposal Considerations**

**Waste Disposal Method:** Incineration is recommended. Waste disposal should be in accordance with existing federal, state and local environmental control laws.

**Section 14: Transportation Information**

**Technical shipping name:** Pharmaceutical

**Domestic Surface Transportation (DOT)**  
**Hazard Class or Division:** Non-Regulated

**Marine Transportation (IMO / IMDG)**  
**Hazard Class Division** Non-Regulated  
**Number:**

**Air Transportation (ICAO / IATA)**  
**Hazard Class Division** Non-Regulated  
**Number:**

**Section 15: Regulatory Information**

**United States Federal Regulations**

**OSHA Hazcom Standard Rating:** Not subject to OSHA

**TSCA Inventory List:** This product is exempt from TSCA Regulation under Section 3 (2)(B)(vi) when used for pharmaceutical application.

**CERCLA Hazardous Substance:**

<u>Component(s)</u>	<u>Reportable Quantity</u>
None	

**SARA Title III**  
**SARA Section 302 Extremely Hazardous Substances:**

<u>Component(s)/</u>	<u>Concentration</u>	
<u>CAS Number</u>	<u>Min.</u>	<u>Max.</u>
Exempt		

**SARA Section 311/312 Hazard Categories:** Exempt from SARA Section 311/312

**SARA Section 313 Toxic Chemicals:**

<u>Component(s)/</u>	<u>Reporting</u>	<u>Concentration</u>	
<u>CAS Number</u>	<u>Threshold</u>	<u>Min.</u>	<u>Max.</u>
Exempt			

**RCRA Status:**

If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

The following chemicals are specifically listed by individual states; other product specific health and safety data in other sections of the MSDS may also be applicable for state requirements. For details on your regulatory requirements you should contact the appropriate agency in your state.

**State Right-to-Know Information**

Component(s)/  
CAS Number

State Code

Concentration  
Min.      Max.

State Code Translation Table

**Section 16: Other Information**

**HMIS Rating**

Health	1
Flammability	1
Reactivity	0

0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe  
\*=Chronic Health Hazard

Bayer Pharmaceuticals Corporation's method of hazard communication is comprised of Product Labels and Material Safety Data Sheets. HMIS and NFPA ratings are provided by Bayer Pharmaceuticals Corporation as a customer service.

Contact: Bill Galdenzi  
Phone: (203) 812-3132  
MSDS Number: 000000000286  
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|| Indicates Relevant Change Made.

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