Section 1. Product and Company Identification

Product Name: Lapatinib Ditosylate Monohydrate
Product ID: L0360
Chemical Name (Synonyms): PR-171
Supplier: LKT Laboratories, Inc
545 Phalen Blvd.
St. Paul, MN 55130 USA
Ph: 651-644-8424 Fax: 651-644-8357
www.lktlabs.com - getinfo@lktlabs.com
Emergency Phone #: 1-800-424-9300

Section 2. Hazards Identification

GHS Classification: Not classified. Caution - substance not yet tested.

GHS Label elements including precautionary statements

Pictogram

Signal word

Hazard and precautionary statements

Hazard statement: Not classified.
Precautionary statement: Not classified.

HMIS Classification
Health hazard: 0
Flammability: 0
Physical hazard: 0

NFPA Rating
Health hazard: 0
Fire hazard: 0
Reactivity hazard: 0

Potential Health Effects
Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.
Skin: May be harmful if absorbed through skin. May cause skin irritation.
Eyes: May cause eye irritation.
Ingestion: May be harmful if swallowed.

Section 3. Composition/Information on Ingredients

| Substances | Ingredient: Title Compound | Percent: 100 |
| Formula     | C_{26}H_{26}ClFN_{4}O_{4}S \cdot 2C_{7}H_{8}O_{3}S \cdot H_{2}O | Formula Wt. 925.46 |
| CAS No.     | 388082-78-8 | EC No. |

Section 4. First Aid Measures

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

Eye Contact
Flush eyes with water as a precaution.

Skin Contact
Wash off with soap and plenty of water.

Inhalation
If breathed in, move person into fresh air. If not breathing, give artificial respiration.

Ingestion
Never give anything by mouth to an unconscious person. Rinse mouth with water.

Section 5. Firefighting Measures

Flash Point
Not available.

Extinguishing Media
Water spray, alcohol-resistant foam, dry chemical powder or carbon dioxide.

Firefighting Procedures
Wear a self-contained breathing apparatus and clothing for firefighting if necessary.

Unusual Fire Hazards
Carbon oxides.

Section 6. Accidental Release Measures

Personal Precautions
Avoid dust formation. Avoid breathing dust, vapors, mist or gas.

Environmental Precautions
Do not let product enter drains.

Methods and materials for containment and cleanup
Avoid raising dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Section 7. Handling and Storage

Handling
Provide appropriate exhaust ventilation at places where dust is formed.

Storage Conditions
Keep container tightly closed in a dry and well-ventilated place. Recommended storage temperature: +4°C.

Hazardous Decomposition Products
Not available.

Other Remarks
None.
Section 8. Exposure Controls/Personal Protection

**Personal protective equipment**

**EXPOSURE CONTROLS**
Contains no substances with occupational exposure limit values.
General industrial hygiene and safety practice.

**PERSONAL PROTECTION**

**Eye/face protection:** Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

**Skin protection:** Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

**Body protection:** Choose body protection in relation to its type, to the concentration and amount of dangerous substances and to the specific workplace.

**Respiratory protection:** Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

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Section 9. Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid</td>
<td>Pale yellow to yellow powder.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Boiling Point</th>
<th>Volatility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not available.</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Melting Point</th>
<th>Density</th>
</tr>
</thead>
<tbody>
<tr>
<td>236-259°C</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Solubility</th>
<th>pH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slightly in DMSO</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flash Point</th>
<th>Ignition temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not available.</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lower explosion limit</th>
<th>Autoignition temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not available.</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Upper explosion limit</th>
<th>Vapor pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not available.</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Water solubility</th>
<th>Odor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not available.</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Partition coefficient: n-octanol/water</th>
<th>Odor Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not available.</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Relative vapor density</th>
<th>Evaporation rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not available.</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

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Section 10. Stability and Reactivity

**Stability**
Stable under recommended storage conditions.

**Materials To Avoid**
Strong oxidizing agents.

**Hazardous Decomposition Products**
Not available.
### Section 11. Toxicological Information

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oral LD50</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Inhalation LC50</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Dermal LD50</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Other information on acute toxicity</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Reproductive Toxicity</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Specific organ toxicity single exposure (GHS)</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Specific organ toxicity repeated exposure (GHS)</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Germ cell mutagenicity</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Aspiration Hazard</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Synergistic effects</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Additional Information</strong></td>
<td>To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.</td>
</tr>
</tbody>
</table>

#### Potential Health Effects
Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.  
Skin: May be harmful if absorbed through skin. May cause skin irritation.  
Eyes: May cause eye irritation.  
Ingestion: May be harmful if swallowed.

#### Carcinogenicity
- **IARC**: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.  
- **ACGIH**: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.  
- **NTP**: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.  
- **OSHA**: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

### Section 12. Ecological Information

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Mobility in soil</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>PBT and vPvB assessment</strong></td>
<td>PBT/vPvB assessment not available as chemical safety assessment not required/ not</td>
</tr>
</tbody>
</table>
Section 13. Disposal Considerations

**Waste Disposal**
Dispose of material according to all federal, state and local regulations.
Offer material to a licensed, professional waste disposal company to dispose of as unused product.

Section 14. Transport Information

**DOT (US)** Not dangerous goods.

**IATA** Not dangerous goods.

**IMDG** Not dangerous goods.

Further Information

Section 15. Regulatory Information

**Reach No.**

**SARA 302 Components** No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313 Components** This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**SARA 311/312 Components** No SARA hazards.

**Massachusetts Right To Know Components** No components are subject to the Massachusetts Right to Know Act.

**Pennsylvania Right To Know Components** Lapatinib Ditosylate Monohydrate CAS #: 388082-78-8 Revision Date:

**New Jersey Right To Know Components** Lapatinib Ditosylate Monohydrate CAS #: 388082-78-8 Revision Date:

**California Prop 65 Components** This product does not contain any chemicals known to State of California to cause cancer, birth defects or any other reproductive harm.

Section 16. Other Information

**Other information** The information in this document is believed to be correct but is not necessarily complete. LKT does not guarantee the accuracy of the information. The burden of verifying the information in this document rests solely upon the user.

Persistence and degradability Not available.

Bioaccumulative potential Not available.

Other adverse effects Not available.