Section I - IDENTIFY

Common/Trade Name: Gefitinib Tablets

Synonyms: N-(3-chloro-4-fluorophenyl)-7-methoxy-6-[3-(4-morpholinyl)propoxy]-4-quinazolinamine;

Manufacturer's Name: GETWELL PHARMACEUTICALS
Address: 474, UDYOG VIHAR, PHASE-V,
GURGAON - 122 016, HARYANA, INDIA

Telephone Number for Info.: +91 124 4014 403 / 04

Date Prepared: April 12, 2017

Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<table>
<thead>
<tr>
<th>CAS # / RTECS #</th>
<th>Hazardous Components (Chemical Name)/ REACH Registration No.</th>
<th>Concentration</th>
<th>EC No./ EC Index No.</th>
<th>GHS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>184475-35-2 VA0952000</td>
<td>Gefitinib</td>
<td>100.0 %</td>
<td>NA NA</td>
<td>Acute Tox.(O) 4: H302 Skin Corr. 2: H315 Eye Damage 1: H318 Carcinogen 2: H351 Toxic Repro. 2: H361 TOST (RE) 2: H373 Aquatic (C) 2: H411</td>
</tr>
</tbody>
</table>
Section III - HEALTH HAZARD DATA

Classification of the Substance or Mixture:
Classification according to Regulation (EC) No 1272/2008 [CLP]:
Acute Toxicity: Oral, Category 4
Skin Corrosion/Irritation, Category 2
Serious Eye Damage/Eye Irritation, Category 1
Carcinogenicity, Category 2
Toxic To Reproduction, Category 2
Target Organ Systemic Toxicity (repeated exposure), Category 2
Aquatic Toxicity (Chronic), Category 2

Label Elements:
Labeling according to Regulation (EC) No 1272/2008 [CLP]:

GHS Signal Word: Danger

GHS Hazard Phrases:
H302: Harmful if swallowed.
H315: Causes skin irritation.
H318: Causes serious eye damage.
H351: Suspected of causing cancer.
H361: Suspected of damaging fertility or the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.
H411: Toxic to aquatic life with long lasting effects.

GHS Precaution Phrases:
P264: Wash {hands} thoroughly after handling.
P280: Wear {protective gloves/protective clothing/eye protection/face protection}.
P362+364: Take off contaminated clothing and wash it before reuse.
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.
P260: Do not breathe {dust/fume/gas/mist/vapours/spray}.
P273: Avoid release to the environment.

GHS Response Phrases:
P301+312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P330: Rinse mouth.
P302+352: IF ON SKIN: Wash with plenty of soap and water.
P332+313: If skin irritation occurs, get medical advice/attention.
P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a {POISON CENTER/doctor/...}.
P308+313: IF exposed or concerned: Get medical attention/advice.
P314: Get medical attention/advice if you feel unwell.
P391: Collect spillage.

**GHS Storage and Disposal Phrases:**
Please refer to Section 7 for Storage and Section 13 for Disposal information.

**Adverse Human Health Effects and Symptoms:**
Causes serious eye damage.
Causes skin irritation.
Harmful if swallowed.
Material may be irritating to the mucous membranes and upper respiratory tract.
May be harmful by inhalation or skin absorption.
May cause damage to organs through prolonged or repeated exposure.
May cause eye or respiratory system irritation.
Suspected of causing cancer.
Suspected of damaging fertility or the unborn child.
Toxic to aquatic life with long lasting effects.
To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

### Section IV - FIRST AID MEASURES

**Description of First Aid** No data available.

**Measures:**
Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

**In Case of Eye Contact:**
Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

**In Case of Skin Contact:**
Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

**In Case of Ingestion:**
Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

### Section V - FIRE AND EXPLOSION HAZARD DATA

**Suitable Extinguishing Media:**
Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.
Use water spray to cool fire-exposed containers.

**Unsuitable Extinguishing Media:**
A solid water stream may be inefficient.

**Flammable Properties and Hazards:** No data available.

**Flash Pt:** No data.

**Explosive Limits:**
<table>
<thead>
<tr>
<th>LEL</th>
<th>UEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>No data</td>
<td>No data</td>
</tr>
</tbody>
</table>

**Autoignition Pt:** No data.

**Fire Fighting Instructions:** As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.
Section VI - ACCIDENTAL RELEASE INFORMATION

Protective Precautions, Protective Equipment and Emergency Procedures:
Avoid raising and breathing dust, and provide adequate ventilation.
As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

Environmental Precautions:
Take steps to avoid release into the environment, if safe to do so.

Methods and Material For Containment and Cleaning Up:
Contain spill and collect, as appropriate.
Transfer to a chemical waste container for disposal in accordance with local regulations.

Section VII - HANDLING AND STORAGE

Precautions To Be Taken in Handling:
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid prolonged or repeated exposure.

Precautions To Be Taken in Storing:
Keep container tightly closed.
Store in accordance with information listed on the product insert.

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Exposure Parameters:

<table>
<thead>
<tr>
<th>CAS #</th>
<th>Partial Chemical Name</th>
<th>Britain EH40</th>
<th>France VL</th>
<th>Europe</th>
</tr>
</thead>
<tbody>
<tr>
<td>184475-35-2</td>
<td>Gefitinib</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
</tr>
<tr>
<td>184475-35-2</td>
<td>Gefitinib</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
</tr>
</tbody>
</table>

Exposure Controls:
Engineering Controls (Ventilation etc.): Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

Personal protection equipment:
Eye Protection: Safety glasses
Protective Gloves: Compatible chemical-resistant gloves
Other Protective Clothing: Lab coat
Respiratory Equipment (Specify Type): NIOSH approved respirator, as conditions warrant.

Work/Hygienic/Maintenance Practices:
Do not take internally.
Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Wash thoroughly after handling.
No data available.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

<table>
<thead>
<tr>
<th>Information on Basic Physical and Chemical Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
</tr>
<tr>
<td>Appearance and Odor</td>
</tr>
<tr>
<td>Melting Point</td>
</tr>
<tr>
<td>Boiling Point</td>
</tr>
<tr>
<td>Property</td>
</tr>
<tr>
<td>--------------------------------------</td>
</tr>
<tr>
<td>Flash Pt</td>
</tr>
<tr>
<td>Evaporation Rate</td>
</tr>
<tr>
<td>Explosive Limits</td>
</tr>
<tr>
<td>Vapor Pressure (vs. Air or mm Hg)</td>
</tr>
<tr>
<td>Vapor Density (vs. Air = 1)</td>
</tr>
<tr>
<td>Specific Gravity (Water = 1)</td>
</tr>
<tr>
<td>Solubility in Water</td>
</tr>
<tr>
<td>Solubility Notes</td>
</tr>
<tr>
<td>Autoignition Pt</td>
</tr>
<tr>
<td>Other Information</td>
</tr>
<tr>
<td>Percent Volatile</td>
</tr>
<tr>
<td>Molecular Formula &amp; Weight</td>
</tr>
</tbody>
</table>

**Section X - STABILITY AND REACTIVITY**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>No data available</td>
</tr>
<tr>
<td>Stability</td>
<td>Unstable [ ] Stable [ X ]</td>
</tr>
<tr>
<td>Stability Note(s):</td>
<td>Stable if stored in accordance with information listed on the product insert. Will occur [ ] Will not occur [ X ]</td>
</tr>
<tr>
<td>Polymerization:</td>
<td></td>
</tr>
<tr>
<td>Conditions To Avoid</td>
<td>No data available</td>
</tr>
<tr>
<td>Incompatibility – Materials To Avoid:</td>
<td>No data available</td>
</tr>
<tr>
<td>Hazardous Decomposition Or Byproducts</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**Section XI - TOXICOLOGICAL INFORMATION**

**Information on Toxicological Effects:**

The toxicological effects of this product have not been thoroughly studied.

**Chronic Toxicological Effects:**

Gefitinib - Toxicity Data: Oral TDLo (human): 3.6 mg/kg; Gefitinib - Investigated as a tumorigen. Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information. Gefitinib RTECS Number: VA0952000.

<table>
<thead>
<tr>
<th>CAS #</th>
<th>Hazardous Components (Chemical Name)</th>
<th>NTP</th>
<th>IARC</th>
<th>ACGIH</th>
<th>OSHA</th>
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<tbody>
<tr>
<td>184475-35-2</td>
<td>Gefitinib</td>
<td>n.a.</td>
<td>n.a.</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
</tbody>
</table>

**Section XII - ECOLOGICAL INFORMATION**

**Toxicity:**
Avoid release into the environment.
Runoff from fire control or dilution water may cause pollution.

**Persistence and Degradability:**
Toxic to aquatic life with long lasting effects.
Bioaccumulative Potential:
No data available.

Mobility in Soil:
No data available.

Results of PBT and vPvB assessment:
No data available.

Section XIII - DISPOSAL INFORMATION

Waste Disposal Method: Dispose in accordance with local, state, and federal regulations.

Section XIV - TRANSPORTATION INFORMATION

LAND TRANSPORT (US DOT):
DOT Proper Shipping Name: Not dangerous goods.
DOT Hazard Class:
UN/NA Number:

LAND TRANSPORT (European ADR/RID):
ADR/RID Shipping Name: Not dangerous goods.
UN Number:
Hazard Class:

AIR TRANSPORT (ICAO/IATA):
ICAO/IATA Shipping Name: Not dangerous goods.

Additional Transport Information:
Transport in accordance with local, state, and federal regulations.

Section XV - REGULATORY INFORMATION

EPA SARA (Superfund Amendments and Reauthorization Act of 1986) Lists

<table>
<thead>
<tr>
<th>CAS #</th>
<th>Hazardous Components (Chemical Name)</th>
<th>S. 302 (EHS)</th>
<th>S. 304 RQ</th>
<th>S. 313 (TRI)</th>
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</thead>
<tbody>
<tr>
<td>184475-35-2</td>
<td>Gefitinib</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS #</th>
<th>Hazardous Components (Chemical Name)</th>
<th>Other US EPA or State Lists</th>
</tr>
</thead>
<tbody>
<tr>
<td>184475-35-2</td>
<td>Gefitinib</td>
<td>CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No</td>
</tr>
</tbody>
</table>

Regulatory Information Statement: This SDS was prepared in accordance with 29 CFR 1910.1200 and Regulation (EC) No.1272/2008.

Section XVI - OTHER DATA

Additional Information About This Product: No data available.

Company Policy or Disclaimer: DISCLAIMER: This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.