Imatinib Mesylate Tablets

Getwell Pharmaceuticals
474, Udyog Vihar, Phase-V,
Gurgaon - 122 016, Haryana, INDIA

Section I  -  IDENTITY

Common/Trade Name: Imatinib Mesylate Tablets

Chemical Names: methanesulfonic acid;4-[(4-methylpiperazin-1-yl)methyl]-N-[4- methyl-3-[(4-pyridin-3-yl)pyrimidin-2-yl]amino]phenyl]benzamide

Synonyms: STI-571; Gleevec; Glivec; CGP57148B; methanesulfonic acid;4-[(4-methylpiperazin-1-yl)methyl]-N-[4-methyl-3-[(4-pyridin-3-yl)pyrimidin-2-yl]amino]phenyl]benzamide

Manufacturer's Name: GETWELL PHARMACEUTICALS
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Date Prepared: February 25, 2017

Section II  -  HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<table>
<thead>
<tr>
<th>Hazardous Components (Chemical Name)</th>
<th>CAS #</th>
<th>Concentration</th>
<th>EC #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imatinib (Mesylate)</td>
<td>220127-57-1</td>
<td>100%</td>
<td>606-892-3</td>
</tr>
</tbody>
</table>

Section III  -  HEALTH HAZARD DATA

PRIMARY ROUTE(S) OF ENTRY:

Oral EFFECTS OF OVEREXPOSURE:
Finished pharmaceutical product. Potential for exposure is reduced in this form. Skin: No hazard is expected from normal clinical use. Eye: No hazard is expected from normal clinical use. Inhalation: No hazard is expected from normal clinical use. Ingestion: No hazard is expected from normal clinical use.

THERAPEUTIC SIDE EFFECTS:
Nausea, vomiting, diarrhea, fluid retention, muscle cramps, skin rash, headache, fatigue, arthralgia, and abdominal pain. TARGET ORGAN EFFECTS: Prolonged or repeated exposure may cause liver and kidney toxicity, and immunosuppresion.
REPRODUCTIVE HAZARDS:
FDA Pregnancy Category D (see section 11). CARCINOGENICITY: Experimental (animal) non- genotoxic carcinogenic effects (see section 11). MUTAGENICITY: Imatinib mesylate was clastogenic in one in vitro assay, and non-mutagenic in three assays.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pregnancy; known hypersensitivity to imatinib or any other components of the formulation; pre-existing liver impairment.

Section IV - FIRST AID MEASURES
In Case of Inhalation:
Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

In Case of Skin 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 Eye Contact:
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 Ingestion:
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.

Section V - FIRE AND EXPLOSION HAZARD DATA
Flash Point: Not applicable
Method Used: Not applicable
Flammable Limits (% in air)
Lower: not applicable
Upper: not applicable
Autoignition: Not available
Temperature: Not available
Extinguishing Media: Use media suitable for fire in surrounding area.
Special Fire Fighting Procedures and Precautions: Evacuate area and fight fire from safe distance.
Fire and Explosion Hazards: Not available
Fire-Fighting Equipment: Wear full protective clothing and positive pressure self-contained breathing apparatus.
Hazardous Products of Combustion: COx, NOx, SOx NFPA
Ratings:
Health = 1
Flammability = 0
Reactivity = 0
Special Hazard = None Hazard Rating
Scales: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe U = Unknown
Section VI - ACCIDENTAL RELEASE INFORMATION

Personal precautions, protective equipment and emergency procedures Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved (or equivalent) self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves). 6.2 Environmental precautions Take steps to avoid release into the environment, if safe to do so. 6.3 Methods and materials 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 - PRECAUTIONS FOR SAFE HANDLING AND USE

Precautions for safe handling Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Conditions for safe storage, including any incompatibilities Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Store under inert gas. Hygroscopic. 7.3 Specific end use(s) Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Control parameters Components with workplace control parameters 8.2 Exposure controls Appropriate engineering controls Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Personal protective equipment Eye/face protection Safety glasses with side-shields conforming to EN166 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. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Body Protection impervious clothing, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Respiratory protection For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). Control of environmental exposure
Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

**Appearance**  powder  
**Odour**  Odourless  
**Melting Point**  226

**Solubility**  Imatinib mesylate shows good aqueous solubility at low pH (<5.5) but is poorly soluble or insoluble at neutral and alkaline pH. In nonaqueous solvents, the drug substance is freely soluble to very slightly soluble in DMSO, methanol, and ethanol but is insoluble in n-octanol, acetone, and acetonitrile.

Section XI - TOXICOLOGICAL INFORMATION

**Acute toxicity**

no data available

**Skin corrosion/irritation**

no data available

**Serious eye damage/eye irritation**

no data available

**Respiratory or skin sensitisation**

Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals. The preceding data, or interpretation of data, was determined using Quantitative Structure Activity Relationship (QSAR) modeling.

**Germ cell mutagenicity**

no data available

**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.

**Reproductive toxicity**

no data available

**Specific target organ toxicity** - single exposure

**Inhalation** - May cause respiratory irritation.
Specific target organ toxicity - repeated exposure

no data available

Aspiration hazard

no data available

Additional Information

RTECS: Not available

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Section XII - ENVIRONMENTAL IMPACT INFORMATION

Bacteria toxicity (respiration inhibition): activated sludge (3h): EC10: 65mg/l EC50: 232mg/l EC80: 605mg/l

Fish toxicity: common carp (cyprinus carpio) (96h): LC0: 56mg/l LC50: 82mg/l

Daphnia toxicity: daphnia magna (water flea) (48h): EC50: 80mg/l NoEC: 32mg/l

Algae toxicity: Selenastrum capricornutum. Green algae. (72h): EbC50: 2.5mg/l EbC10: 1.1mg/l NoEC: 0.96mg/l

Biological elimination: 9 - 12% (aerobic) (28d) Inhibitory effects can be excluded. Bioaccumulation in water organisms is not likely based on the n-octanol/water partition coefficient (log pOW < 3.0). Avoid release into the environment

Temozolomide is not readily biodegradable. Temozolomide did not meet the 10-day window to meet the criteria for ready biodegradability, but did degrade 79% by day 28. Temozolomide did hydrolyze, within 2 hours, into AIC the primary degradation product in the environment and the human body

Section XIII - DISPOSAL INFORMATION

Using appropriate protective equipment, absorb/sweep up and containerize spilled material. All wastes must be disposed of in accordance with local, state and federal laws and regulations. Avoid disposal in sewers and waterways.

Section XIV - TRANSPORTATION INFORMATION

Using appropriate protective equipment, absorb/sweep up and containerize spilled material. All wastes must be disposed of in accordance with local, state and federal laws and regulations. Avoid disposal in sewers and waterways.

Section XV - REGULATORY INFORMATION

This product has been classified in accordance with the hazard criteria of Controlled product regulations and the MSDS contains all the information required by controlled product regulations.
Section XVI - OTHER DATA

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Getwell Pharmaceuticals shall not be held liable for any damage resulting from handling or from contact with the above product.

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