

# Material Safety Data Sheet

## (MSDS)

In accordance with GHS Rev. 9

### Section 1 - Chemical Product and Company Identification

#### 1.1 Product Identification:

Product Name: Sorafenib Tablets  
Product Model: 200mg

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses: Treatment of inoperable or metastatic hepatocellular carcinoma.  
Use advised against: No data available.

#### 1.3 Details of the Manufacture or supplier

Manufacture: Yabao Pharmaceutical Co., Ltd. Beijing.  
Address: 97 Kechuang East 6th Street, BDA, Beijing, China.  
Telephone: +86-10-58086000  
Fax: +86-10-58056013  
E-mail: lishaochun@yabaoyaoye.com.

#### 1.4 Emergency telephone number

Emergency Telephone: +86-10-58086000

### Section 2 - Hazards Identification

#### 2.1 Classification of the substance or mixture

**GHS Classification:** Reproductive toxicity, categories 1B  
Specific target organ toxicity - Repeated exposure, Category 2 (central and peripheral nervous system )

#### 2.2 GHS Label elements, including precautionary statements

**GHS Labels:**

**Pictogram(s):**



**Signal Word:** Danger

**Hazard Statement:** H360: May damage fertility or the unborn child

H373: May cause damage to organs(central and peripheral nervous system) through prolonged or repeated exposure.

**Precautionary statement(s)**

**Prevention precautionary statements:** P201: Obtain special instructions before use  
P202: Do not handle until all safety precautions have been read and understood  
P260: Do not breathe dust/fume/gas/mist/vapours/spray.  
P281: Use personal protective equipment as required

**Response Precautionary Statements:** P314: Get medical advice/attention if you feel unwell.  
P308+313: IF exposed or concerned: Get medical advice/attention

**Storage Precautionary Statements:** P405: Store locked up

**Disposal Precautionary Statements:** P501: Dispose of contents and container in accordance with local/regional/national /international regulations.

**2.3 Description of any hazards not otherwise classified**

None. See section 11 for more detailed information on health effects and symptoms.

**Section 3 - Composition/Information on Ingredient**

Substance ( ) Preparation ( ✓ ) Article ( )

Composition:

Component	CAS No.	Content (w/w%)
Sorafenib Tosylate (Micronized)	475207-59-1	77.49%
Microcrystalline Cellulose, NF (Avicel PH-101)	9004-34-6	10.68%
Croscarmellose Sodium, NF (Ac-Di-Sol)	74811-65-7	5.77%
Hypromellose,NF (Methocel E50)	9004-65-3	0.96%
Sodium Lauryl Sulfate, NF	151-21-3	0.29%
Magnesium Stearate, NF	557-04-0	0.96%
Opadry 03F640025Pink	-	3.85%

Abbreviation: CAS No. is Chemical Abstract Service Registry Number.

**Section 4 - First Aid Measures**

**4.1 Description of first aid measures:**

**Inhalation:** No need for first aid is anticipated(The product is a tablet and will not be inhaled under normal

circumstances).

**Skin Contact:** Not considered to have any adverse properties affecting skin. No need for first aid is anticipated.

**Eye Contact:** Flush eyes with water as a precaution.

**Ingestion:** If medication symptoms without improvement after several days, or symptoms increased, or the emergence of new serious symptoms, should be discontinued, and go to hospital for treatment.

#### **4.2 Most important symptoms and effects, both acute and delayed**

No information available.

#### **4.3 Indication of any immediate medical attention and special treatment needed**

Treat according to the symptoms.

## **Section 5 -Extinguishing media**

### **5.1 Extinguishing media**

**Suitable extinguishing media:** Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**Unsuitable extinguishing media:** None known.

### **5.2 Special hazards arising from the substance or mixture**

Overheat may produce decomposition products: Carbon oxides, nitrogen oxides, sulfur oxides, hydrogen chloride, hydrogen fluoride, hydrogen bromide, etc.

### **5.3 Advice for firefighters**

As in any fire, Wear self-contained breathing apparatus and full protective gear for firefighting.

### **5.4 Further information**

No data available.

## **Section 6 - Accidental Release Measures**

For guidance on selection of personal protective equipment see Chapter 8 of this Material Safety Data Sheet. See Chapter 13 for information on disposal. Observe the relevant local and international regulations.

### **6.1 Personal precautions, protective equipment and emergency procedures:**

No special requirements.

### **6.2 Environmental precautions:**

Avoid release to environment.

### **6.3 Methods and materials for containment and cleaning up:**

Pick up or sweep up mechanically.

## Section 7 - Handling and Storage

### 7.1 Precautions for safe handling:

Follow the product instructions and take the medicine under the guidance of a doctor.

Keep away from direct heat sources(eg., radiators, sunlight, etc.)

Keep out of reach of children.

Instructions for use: At least 2 hours before the light diet or 2 hours after the fasting (ie, no food and drink, except for water), oral administration by a cup of warm water, the whole capsule is swallowed and should not be chewed or opened.

### 7.2 Conditions for safe storage, including any incompatibilities:

Keep container tightly closed in cool, dry place. Keep away from direct heat sources(eg., radiators, sunlight, etc.)

## Section 8 - Exposure Controls, Personal Protection

**8.1 Exposure Limits:** Not established.

### 8.2 Exposure controls

**Engineering Control:** No special measures required.

### Personal protective equipment:

**Respiratory Protection:** Not required for consumer under normal usage.

**Eyes Protection:** Not required for consumer under normal usage.

**Body Protection:** Not required for consumer under normal usage.

**Hands Protection:** Not required for consumer under normal usage. Wear resistant gloves in production.

**Other Protections:** Not required for consumer under normal usage.

## Section 9 - Physical and Chemical Properties

### Information on basic physical and chemical properties

<b>Appearance</b>	Solid, circular tablets
<b>Color</b>	Pink
<b>Odor</b>	Odorless
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.

<b>Flammability</b>	Not flammable.
<b>Upper explosive limit %(V/V)</b>	Not available.
<b>Lower explosive limit %(V/V)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	Not available.
<b>Partition coefficient: n-octanol/water</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## Section 10 - Stability and Reactivity

**10.1 Stability:** Stable under normal storage temperature and pressure.

**10.2 Conditions to Avoid:** Keep away from open flames, hot surfaces, and sources of ignition.

**10.3 Incompatible materials:** Strong oxidizing agents, non-food chemicals.

**10.4 Hazardous Decomposition Products:** Other decomposition products- no data available. In the event of fire:see section 5.

**10.5 Possibility of hazardous reactions:** None hazardous reactions known under normal condition.

## Section 11 - Toxicological Information

<b>Acute Toxicity:</b>	No data available.
<b>Skin Corrosion/Irritation:</b>	No known irritating effect.
<b>Serious Eye Damage/Eye Irritation:</b>	No known irritating effect.
<b>Respiratory or Skin Sensitization</b>	No sensitizing effects known.
<b>Germ Cell Mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity:</b>	None of the components of this product is listed as a carcinogen by IARC, NTP, US OSHA.
<b>Reproductive Toxicity:</b>	May damage fertility or the unborn child.
<b>Specific Target Organ Toxicity - Single Exposure (Globally Harmonized System):</b>	No known human health effects upon single exposure.
<b>Specific Target Organ Toxicity - Repeated Exposure (Globally Harmonized System):</b>	May cause damage to organs(central and peripheral nervous system) through prolonged or repeated exposure.

<b>Aspiration Hazard:</b>	Based on available data, the classification criteria are not met.
<b>Potential Health Effects:</b>	
<b>Inhalation:</b>	No hazardous volatiles or dust can be inhaled under normal usage.
<b>Skin Contact:</b>	No hazards to skin.
<b>Eye Contact:</b>	No hazards to eyes.
<b>Ingestion:</b>	Harmful if ingested. This product generally is regarded as safe if taken according product instruction and doctor's advice.

## Section 12 - Ecological Information

### 12.1 Toxicity

No data available

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

No bioaccumulative potential

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Other adverse effects

Prevent large quantities from contacting waterways.

## Section 13 - Disposal Considerations

### Waste treatment methods

#### Product

Recycle if possible. Offer surplus and non-recyclable products to a licensed disposal company. Observe according to the national and local related regulations.

#### Contaminated packaging

Dispose of as unused product after empty.

## Section 14 - Transport Information

#### 14.1 UN-Number

ADR/RID/ADN, IMO/IMDG, IATA Not applicable.

#### 14.2 UN proper shipping name

ADR/RID/ADN, IMO/IMDG, IATA Not applicable.

#### 14.3 Transport hazard class(es)

ADR/RID/ADN, IMO/IMDG, IATA

Class Not applicable.

Label Not applicable.

#### 14.4 Packing group

ADR/RID/ADN, IMO/IMDG, IATA Not applicable.

#### 14.5 Environmental hazards

Not applicable.

#### 14.6 Special precautions for user

Not applicable.

#### 14.7 Transport in bulk according to Annex 1 of

Marpol and the IBC Code

Not applicable.

#### 14.8 Transport/Additional information:

Not dangerous according to the above specifications.

UN 'Model Regulation':

Not applicable.

### Section 15 - Regulatory Information

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

No data available.

#### 15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

### Section 16 - Additional Information

#### 16.1 Reference

- [1] IPCS: The International Chemical Safety Cards website: <http://www.ilo.org/dyn/icsc/showcard.home>  
(ICSC)
- [2] EU REACH Registered Substance Database website:  
<http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

- |     |  |   |
|-----|--|---|
| [3] | OECD: The Global Portal to Information on Chemical Substances, | website:<br><a href="http://www.echemportal.org/echemportal/index?pageID=0&amp;request_locale=en">http://www.echemportal.org/echemportal/index?pageID=0&amp;request_locale=en</a> |
| [4] | CAMEO Chemicals,   | website: <a href="http://cameochemicals.noaa.gov/search/simple">http://cameochemicals.noaa.gov/search/simple</a>  |
| [5] | NLM:ChemIDplus,  | website:<br><a href="http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp">http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp</a>   |
| [6] | EPA: Integrated Risk Information System,                       | website: <a href="http://cfpub.epa.gov/iris/">http://cfpub.epa.gov/iris/</a>  |
| [7] | U.S. Department of Transportation:ERG,                         | website: <a href="http://www.phmsa.dot.gov/hazmat/library/erg">http://www.phmsa.dot.gov/hazmat/library/erg</a>  |
| [8] | Germany GESTIS-database on hazard substance                    | website: <a href="http://gestis-en.itrust.de/">http://gestis-en.itrust.de/</a>  |
| [9] | IARC   | website: <a href="http://www.iarc.fr/">http://www.iarc.fr/</a>  |

## 16.2 Abbreviations and acronyms

PC-STEL	Short term exposure limit
PC-TWA	Time Weighted Average
IARC	International Agency for Research on Cancer
LC50	Lethal Concentration 50%
LD50	Lethal Dose 50%
EC50	Effective Concentration 50%
PBT	Persistent, Bioaccumulative, Toxic
vPvB	very Persistent, very Bioaccumulative
ADR	Agreement on Dangerous Goods by Road
IATA	International Air Transport Association
IMO	International Maritime Organization
IMDG	The International Maritime Dangerous Goods
ICAO	International Civil Aviation Organization
UN	The United Nations
NTP	National Toxicology Program
ACGIH	The American Conference of Governmental Industrial Hygienists
OSHA	Occupational Safety and Health Administration
NIOSH	National Institute for Occupational Safety and Health

## 16.3 Disclaimer

-This safety data sheet was prepared in accordance with UN GHS Rev.9.

-The data included was derived from international authoritative database and provided by the enterprise. Other information was based on the present state of our knowledge. We try to ensure the correctness of all information. However, due to the diversity of information sources and the limitations of our knowledge, this document is only for user's reference. Users should make their independent judgment of suitability of this information for their particular purposes. We do not assume responsibility for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product

## 16.4 Information on revision

MSDS Creation Date:	November 14, 2022
MSDS Revision Date:	-
Reason For Revision:	-



MSDS Edition: 1.0

\*\*\*End of MSDS\*\*\*