

# SAFETY DATA SHEETS

According to the UN GHS revision 10

## 1: Identification

### 1.1 GHS Product identifier

Product name Macitentan

### 1.2 Other means of identification

Product number 441798-33-0

Other names Macitentan

### 1.3 Recommended use of the chemical and restrictions on use

Identified uses Industrial and scientific research use.

Uses advised against no data available

### 1.4 Supplier's details

Company Zhongshan Greenrock Technology Co., Ltd.

Address No. 138, Jinsan Avenue, Sanjiao Town, Zhongshan City, Guangdong Province, China

Telephone +86-2087066781

### 1.5 Emergency phone number

Emergency phone number +86-2087066781

Service hours Monday to Friday, 9am-5pm (Standard time zone: UTC/GMT +8 hours).

## 2: Hazard identification

### 2.1 Emergency Overview

Substances with long-term health risks may cause cancer, gene mutations, or reproductive system damage. Even short-term exposure may have long-term health effects and exposure must be strictly controlled.

### 2.2 GHS Classification

Reproductive toxicity : Category 1, 1A, 1B

### 2.3 GHS label elements, including precautionary statements

Pictogram(s)



|                                   |   |
|-----------------------------------|---|
| <b>Signal word</b>                | Danger  |
| <b>Hazard statement(s)</b>        | H360 May damage fertility or the unborn child   |
| <b>Precautionary statement(s)</b> |   |
| <b>Prevention</b>                 | P203 Obtain, read and follow all safety instructions before use.<br>P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/... |
| <b>Response</b>                   | P318 if exposed or concerned, get medical advice.   |
| <b>Storage</b>                    | P405 Store locked up.   |
| <b>Disposal</b>                   | P501 Dispose of contents/container to ...   |

## 2.4 Physical and chemical

Although they may not be immediately dangerous, some substances may also be irritants or corrosives. They may decompose and produce more toxic products during long-term storage.

## 2.5 Health hazards

Carcinogenicity, Long-term exposure may increase the risk of cancer. Mutagenicity: May cause genetic damage, affecting offspring. Reproductive toxicity: May affect fertility or cause fetal malformations. Symptoms typically appear after a latent period of several years.

## 2.6 Environmental hazards

May persist and accumulate in the environment. Chronic toxicity to aquatic and terrestrial organisms can affect their reproductive capacity. It may accumulate through the food chain, ultimately affecting human health.

## 2.7 Other hazards which do not result in classification

no data available

# 3: Composition/information on ingredients

## 3.1 Substances

| Chemical name | Common names and synonyms | CAS number  | EC number | Concentration |
|---------------|---------------------------|-------------|-----------|---------------|
| Macitentan    | Macitentan                | 441798-33-0 | 810-007-8 | 99%           |

# 4: First-aid measures

## 4.1 General advice

Stop contact immediately and remove contaminated clothing (rinse with clean water and then wash); wash skin with soap and water, record contact history (including contact time and frequency); and have regular physical examinations (such as chest CT and blood routine once a year).

## 4.2 If inhaled

Move to fresh air. If carcinogenic gases (such as benzene) are inhaled and coughing or chest tightness occurs, seek medical attention. Those with long-term exposure need to monitor lung function and blood routine.

#### **4.3 In case of skin contact**

Rinse with soap and running water for 15 minutes. If skin is irritated, apply a non-irritating moisturizer; avoid breaking the skin to prevent penetration of substances.

#### **4.4 In case of eye contact**

Rinse with saline for 10 minutes and then instill artificial tears; if discomfort persists, seek medical attention from an ophthalmologist.

#### **4.5 If swallowed**

Do not induce vomiting, seek medical attention immediately, and bring the substance's SDS; inform the doctor of the substance's carcinogenic/mutagenic properties and perform a gastrointestinal endoscopy if necessary.

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

Acute symptoms: mild skin/eye irritation; long-term effects: carcinogenicity (such as lung cancer, leukemia), mutagenicity (chromosomal abnormalities), reproductive toxicity (infertility, fetal malformations).

#### **4.7 Protection of first-aiders**

Rescuers need to wear chemical protective clothing, gas masks (equipped with organic vapor filter cartridges), and chemical protective gloves; equipment must be thoroughly cleaned after contact to avoid residue.

#### **4.8 Notes to physician**

Inform the doctor of the substance name and exposure history; long-term exposure requires a special physical examination plan (such as blood tests every 6 months and tumor markers every year)

## **5: Fire-fighting measures**

### **5.1 Unsuitable extinguishing media**

It is strictly forbidden to use fire extinguishing agents that may cause the spread of toxic substances (such as high-pressure water jets); if it contains flammable ingredients, avoid using carbon dioxide (concentrated toxic vapor).

### **5.2 Specific hazards during fire fighting**

Combustion releases carcinogenic/mutagenic gases (such as benzopyrene and formaldehyde), which are harmful to health if exposed for a long time. The combustion products of some substances are easily adsorbed on dust, expanding the scope of pollution. Toxic substances are not easy to decompose and require professional handling after fire extinguishing.

### **5.3 Hazardous combustion products**

Polycyclic aromatic hydrocarbons (carcinogenic), formaldehyde (mutagenic), heavy metal smoke (such as chromium, nickel), chlorides (when containing chlorine).

## **5.4 Specific extinguishing methods**

Small area: Use dry powder/foam to extinguish the fire, and use water mist to dilute the toxic vapor; Large area: Evacuate personnel, if fire must be extinguished, cover with foam (to reduce vapor release); After extinguishing the fire, conduct toxicity testing on the area and dispose of pollutants as hazardous waste.

## **5.5 Special protective equipment for fire-fighters**

Wear chemical protective clothing, positive pressure air respirator, and chemical protective gloves; carry a toxic gas detector (to detect benzene, formaldehyde, etc.); wear a dust mask (to protect against toxic dust) during work, and conduct a health check after work.

# **6: Accidental release measures**

## **6.1 Protective measures for workers**

Wear fully enclosed chemical protective clothing, positive pressure respirator (volatile), toxic-resistant gloves + goggles; workers should undergo regular physical examinations and record their exposure history; eating, drinking and smoking are prohibited.

## **6.2 Environmental protection measure**

Isolate the contaminated area within 20 meters and conduct long-term environmental monitoring (soil/air); leaks are prohibited from being discarded at will; the contaminated area must be released after passing the inspection by the environmental protection department.

## **6.3 Containment methods for leaked chemicals**

Liquids should be collected in disposable corrosion-resistant containers (marked with hazard categories); solids should be collected in chemical-resistant bags (to prevent dust); and stored separately in dedicated hazardous waste warehouses.

## **6.4 Cleanup methods for chemical spills**

Small leakage: absorbed by special adsorption materials and then packaged in chemical-proof bags; large leakage: transferred by professional team using special equipment; after cleaning, the ground is treated with disinfectant.

## **6.5 Measures to prevent the spread of leaks**

20-meter isolation zone + warning signs; high-efficiency filtration and ventilation (volatile); chemical isolation belt to prevent spread to residential areas.

## **6.6 Container leakage treatment**

Minor leaks: seal with professional sealant + tightness test; serious leaks: evacuate, transfer by professional team, and dispose of the container as hazardous waste.

## **6.7 Special considerations**

Operators need special training; protective equipment must be disinfected and tested before reuse; leak handling must be reported to the environmental protection department.

## 7: Handling and storage

### 7.1 Safe storage conditions

Stored in a closed, leak-proof warehouse (walls lined with polyethylene film and floors with impermeable resin); containers are made of non-degradable materials (such as high-density polyethylene, borosilicate glass) with anti-theft lids (requires a key to open); the warehouse is equipped with an air purification system (HEPA filter, filtration efficiency >99.97%).

### 7.2 Storage precautions

Isolate from children and unrelated personnel, and place biohazard signs at the warehouse entrance; store separately to avoid mixing with other chemicals; test the concentration of hazardous substances in the warehouse every quarter to ensure that it is below the occupational exposure limit (such as carcinogen OEL > 0.01mg/m<sup>3</sup>); discarded containers must be sterilized at high temperature (>121°, 30 minutes) before disposal.

### 7.3 VCI Storage Grade

Level 4 (lowest): Metal containers are treated with ordinary anti-rust treatment (such as galvanizing, thickness > 10µm) and corrosion is checked once a year; the humidity in the warehouse is controlled at 45%-65% to avoid damage to the containers due to moisture.

### 7.4 Recommended storage temperature

Store at 10-30°C, away from light (e.g., some photosensitive carcinogens must be stored in brown containers); easily degradable substances (e.g., some organic carcinogens) must be stored at >25°C, equipped with light-proof and sun-shading facilities; long-term storage (over 1 year) requires the stability of the substance to be checked every 3 months (if the label has a recommended storage temperature, follow the label).

### 7.5 Handling

For precautions see Safety Data Sheet section 2

Advice on safe handling : Work under hood. Do not inhale substance/mixture.

## 8: Exposure controls/personal protection

### 8.1 Respiratory protection

When exposed to carcinogens (such as benzene and formaldehyde) for a long time, wear a powered air-purifying respirator (APF>50); dust (such as asbestos) requires Type P100 filter cotton to ensure no leakage.

### 8.2 Recommended Filter type

For organic carcinogens, choose Type A2 filter cartridge; for inorganic carcinogenic gases (such as arsine), choose Type E+K composite filter cartridge; for dust, choose Type P100 filter cotton.

### 8.3 Eye/face protection

Wear chemical protection goggles + protective mask. The mask material should be resistant to toxic penetration. The lenses need to be replaced regularly for long-term work (to prevent aging).

## 8.4 Skin and body protection

Wear impermeable chemical protective clothing made of polyethylene + aluminum foil coating (anti-organic vapor penetration); avoid skin damage during operation to prevent material intrusion.

## 8.5 Hand protection

Wear toxic and chemical-resistant gloves made of butyl rubber or fluororubber. Gloves need to be regularly tested for penetration (once every three months) and replaced immediately if unqualified.

## 8.6 Hygiene measures

After work, clean the skin with a special detergent (such as a neutral surfactant), then rinse with running water for 10 minutes; clothes must be washed separately and must not be mixed with household clothes; undergo special physical examinations every year (such as chest CT, chromosome examination).

# 9: Physical and chemical properties and safety characteristics

|   |                       |
|---|-----------------------|
| <b>Physical state</b>   | no data available     |
| <b>Colour</b>   | no data available     |
| <b>Odour</b>  | no data available     |
| <b>Melting point/freezing point</b>                             | 134-136°C             |
| <b>Boiling point or initial boiling point and boiling range</b> | 692.397°C at 760 mmHg |
| <b>Flammability</b>   | no data available     |
| <b>Lower and upper explosion limit/flammability limit</b>       | no data available     |
| <b>Flash point</b>  | 372.548°C             |
| <b>Auto-ignition temperature</b>                                | no data available     |
| <b>Decomposition temperature</b>                                | no data available     |
| <b>pH</b>   | no data available     |
| <b>Kinematic viscosity</b>                                      | no data available     |
| <b>Solubility</b>   | no data available     |
| <b>Partition coefficient n-octanol/water</b>                    | no data available     |
| <b>Vapour pressure</b>  | no data available     |

|  |                   |
|--|-------------------|
| <b>Density and/or relative density</b> | 1.675             |
| <b>Relative vapour density</b>         | no data available |
| <b>Particle characteristics</b>        | no data available |

## 10: Stability and reactivity

### 10.1 Reactivity

no data available

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

no data available

### 10.4 Conditions to avoid

no data available

### 10.5 Incompatible materials

no data available

### 10.6 Hazardous decomposition products

no data available

## 11: Toxicological information

### 11.1 Acute toxicity

Oral: no data available

Inhalation: no data available

Dermal: no data available

### 11.2 Skin corrosion/irritation

no data available

### 11.3 Serious eye damage/irritation

no data available

### 11.4 Respiratory or skin sensitization

no data available

### **11.5 Germ cell mutagenicity**

no data available

### **11.6 Carcinogenicity**

no data available

### **11.7 Reproductive toxicity**

no data available

### **11.8 STOT-single exposure**

no data available

### **11.9 STOT-repeated exposure**

no data available

### **11.10 Aspiration hazard**

no data available

## **12: Ecological information**

### **12.1 Toxicity**

Toxicity to fish: no data available

Toxicity to daphnia and other aquatic invertebrates: no data available

Toxicity to algae: no data available

Toxicity to microorganisms: no data available

### **12.2 Persistence and degradability**

no data available

### **12.3 Bioaccumulative potential**

no data available

### **12.4 Mobility in soil**

no data available

### **12.5 Other adverse effects**

no data available

## **13: Disposal considerations**

## 13.1 Disposal methods for waste chemicals

It must be handled by an organization with hazardous waste disposal qualifications, with high-temperature incineration (temperature  $\geq 900^{\circ}\text{C}$ ) being preferred to completely destroy hazardous substances. Waste that cannot be incinerated must be chemically degraded or stabilized before being safely landfilled. Contaminated containers must be sterilized at high temperatures or chemically before disposal.

## 13.2 Precautions

Disposal personnel must wear special protective equipment and undergo regular health checks; waste must be tightly sealed to prevent leakage; waste gas and wastewater generated during the disposal process must undergo special treatment to ensure compliance with standards; disposal records must be kept for a long time (at least 30 years); and mixing with ordinary waste is prohibited.

## 14: Transport information

### 14.1 UN Number

ADR/RID: no data available      IMDG: no data available      IATA: no data available

### 14.2 UN Proper Shipping Name

ADR/RID: no data available      IMDG: no data available      IATA: no data available

### 14.3 Transport hazard class(es)

ADR/RID: no data available      IMDG: no data available      IATA: no data available

### 14.4 Packing group, if applicable

ADR/RID: no data available      IMDG: no data available      IATA: no data available

### 14.5 Environmental hazards

ADR/RID: no      IMDG: no      IATA: no

### 14.6 Special precautions for user

no data available

### 14.7 Transport in bulk according to IMO instruments

no data available

## 15: Regulatory information

### 15.1 Safety, health and environmental regulations specific for the product in question

| Chemical name | Common names and synonyms | CAS number  | EC number |
|---------------|---------------------------|-------------|-----------|
| Macitentan    | Macitentan                | 441798-33-0 | 810-007-8 |

|   |             |
|---|-------------|
| <b>New Zealand Inventory of Chemicals (NZIoC)</b>                         | Not Listed. |
| <b>Philippines Inventory of Chemicals and Chemical Substances (PICCS)</b> | Not Listed. |
| <b>Vietnam National Chemical Inventory</b>                                | Not Listed. |
| <b>Australian Inventory of Industrial Chemicals (AIIC)</b>                | Not Listed. |
| <b>Catalogue of Strictly Restricted Toxic Chemicals in China</b>          | Not Listed. |
| <b>China Catalog of Hazardous chemicals 2015</b>                          | Not Listed. |
| <b>European INventory of Existing Commercial chemical Substances</b>      | Not Listed. |
| <b>IARC Monographs on the Evaluation of Carcinogenic Risks to Humans</b>  | Not Listed. |
| <b>TSCA Inventory of Chemical Substances</b>                              | Not Listed. |

## 16: Other information

### Information on revision

**SDS Creation Date** July 1, 2025

**SDS Revision Date** July 1, 2025

### Abbreviations and acronyms in SDS

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

### SDS References

- IPCS - The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>
- HSDB - Hazardous Substances Data Bank, website: <https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>
- IARC - International Agency for Research on Cancer, website: <http://www.iarc.fr/>
- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: [http://www.echemportal.org/echemportal/index?pageID=0&request\\_locale=en](http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en)
- CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>
- ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>
- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: <http://www.phmsa.dot.gov/hazmat/library/erg>
- Germany GESTIS-database on hazard substance, website: <http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp>
- ECHA - European Chemicals Agency, website: <https://echa.europa.eu/>

**Any questions regarding this Safety Data Sheet, Please send your inquiry to [sales@MolBest.com](mailto:sales@MolBest.com)**

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