# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519

Mianserin Formulation

## 1. PRODUCT AND COMPANY IDENTIFICATION

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1.5</td>
<td>2019/09/13</td>
<td>1601112-00006</td>
<td>2019/04/24</td>
<td>2017/05/01</td>
</tr>
</tbody>
</table>

### Product name
- Mianserin Formulation

### Manufacturer or supplier’s details
- **Company**: Organon & Co.
- **Address**: 30 Hudson Street, 33nd floor, Jersey City, New Jersey, U.S.A 07302
- **Telephone**: 551-430-6000
- **Emergency telephone number**: 215-631-6999
- **E-mail address**: EHSSTEWARD@organon.com

### Recommended use of the chemical and restrictions on use
- **Recommended use**: Pharmaceutical

## 2. HAZARDS IDENTIFICATION

### Emergency Overview
- **Appearance**: Crystalline solid
- **Colour**: white to off-white
- **Odour**: No data available

Suspected of damaging fertility. Suspected of damaging the unborn child. Causes damage to organs.

### GHS Classification
- **Reproductive toxicity**: Category 2
- **Specific target organ toxicity - single exposure**: Category 1

### GHS label elements
- **Hazard pictograms**: [Image]
- **Signal word**: Danger
- **Hazard statements**: H361fd Suspected of damaging fertility. Suspected of damaging the unborn child. H370 Causes damage to organs.
- **Precautionary statements**: **Prevention:**
  - P201 Obtain special instructions before use.
  - P202 Do not handle until all safety precautions have been read
Physical and chemical hazards
Not classified based on available information.

Health hazards
Suspected of damaging fertility. Suspected of damaging the unborn child. Causes damage to organs.

Environmental hazards
Not classified based on available information.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>mianserin hydrochloride</td>
<td>21535-47-7</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse.
In case of eye contact: Thoroughly clean shoes before reuse.

Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed:

Suspected of damaging fertility. Suspected of damaging the unborn child.

Causes damage to organs.

Protection of first-aiders:

First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician:

Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray

Alcohol-resistant foam

Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products:

Carbon oxides

Metal oxides

Oxides of phosphorus

Silicon oxides

Specific extinguishing methods:

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do so.

Evacuate area.

Special protective equipment for firefighters:

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment.

Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided.

Prevent further leakage or spillage if safe to do so.

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal.

Local or national regulations may apply to releases and dis-
posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Handling
Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: Use only with adequate ventilation.
Advice on safe handling: Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Take care to prevent spills, waste and minimize release to the environment.
Avoidance of contact: Oxidizing agents

Storage
Conditions for safe storage: Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
Materials to avoid: Do not store with the following product types: Strong oxidizing agents
Packaging material: Unsuitable material; None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>mianserin hydrochloride</td>
<td>21535-47-7</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
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</table>

Further information: Skin Wipe limit 200 µg/100 cm² Internal

Engineering measures: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

Personal protective equipment
Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type: Particulates type
Eye/face protection: Wear the following personal protective equipment:
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Safety glasses

Skin and body protection
Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Hand protection

Material: Chemical-resistant gloves

Remarks: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer.

Hygiene measures
If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Crystalline solid
Colour: white to off-white
Odour: No data available
Odour Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: Not applicable
Evaporation rate: No data available
Flammability (solid, gas): Not classified as a flammability hazard
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : No data available
Density : No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : Not applicable
Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
 Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes : Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method
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Components:

mianserin hydrochloride:
Acute oral toxicity: LD50 (Rat): 780 mg/kg
LD50 (Mouse): 224 mg/kg
Acute toxicity (other routes of administration): LD50 (Mouse): 32 mg/kg
Application Route: Intravenous

Starch:
Acute oral toxicity: LD50 (Mouse): > 5,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

mianserin hydrochloride:
Remarks: Not classified due to lack of data.

Serious eye damage/eye irritation
Not classified based on available information.

Components:

mianserin hydrochloride:
Remarks: Not classified due to lack of data.

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

mianserin hydrochloride:
Remarks: Not classified due to lack of data.

Germ cell mutagenicity
Not classified based on available information.

Components:

mianserin hydrochloride:
Genotoxicity in vitro: Test Type: gene mutation test
Result: positive
Test Type: Bacterial reverse mutation assay (AMES)
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- **Result**: negative
- **Remarks**: Based on data from similar materials

- **Test Type**: sister chromatid exchange assay
- **Result**: negative
- **Remarks**: Based on data from similar materials

- **Test Type**: In vitro mammalian cell gene mutation test
- **Result**: negative
- **Remarks**: Based on data from similar materials

- **Test Type**: unscheduled DNA synthesis assay
- **Result**: negative
- **Remarks**: Based on data from similar materials

**Genotoxicity in vivo**
- **Test Type**: Micronucleus test
- **Species**: Rat
- **Cell type**: Bone marrow
- **Application Route**: Oral
- **Result**: negative
- **Remarks**: Based on data from similar materials

**Carcinogenicity**
Not classified based on available information.

**Components:**

- **mianserin hydrochloride**
- **Remarks**: Not classified due to lack of data.

**Reproductive toxicity**
Suspected of damaging fertility. Suspected of damaging the unborn child.

**Components:**

- **mianserin hydrochloride**
- **Effects on fertility**
  - **Test Type**: Fertility
  - **Species**: Rat, male
  - **Fertility**: NOAEL: 100 mg/kg body weight
  - **Result**: No effects on fertility, No effects on mating performance

  - **Test Type**: Fertility
  - **Species**: Rat, female
  - **Fertility**: LOAEL: 30 mg/kg body weight
  - **Result**: Preimplantation loss, ovarian dysfunction, Effect on estrous cycle

- **Effects on foetal development**
  - **Test Type**: Development
  - **Species**: Rat
  - **Application Route**: Subcutaneous
  - **Developmental Toxicity**: LOAEL: 10 mg/kg body weight
  - **Result**: Effects on postnatal development
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Test Type: Development  
Species: Rat  
Developmental Toxicity: LOAEL: 3 mg/kg body weight  
Result: Embryolethal effects, No teratogenic effects

Test Type: Development  
Species: Rabbit  
Result: Reduced foetal weight, No teratogenic effects

Test Type: Development  
Species: Mouse  
Developmental Toxicity: NOAEL: 30 mg/kg body weight  
Result: No effects on foetal development

Reproductive toxicity - Assessment: Suspected of damaging fertility. Suspected of damaging the unborn child.

**STOT - single exposure**  
Causes damage to organs.

**Components:**

mianserin hydrochloride:  
Target Organs: Central nervous system  
Assessment: Causes damage to organs.

**STOT - repeated exposure**  
Not classified based on available information.

**Repeated dose toxicity**

**Components:**

mianserin hydrochloride:  
Species: Rat  
NOAEL: 30 mg/kg  
Application Route: Oral  
Exposure time: 6 Months  
Remarks: No significant adverse effects were reported

Species: Dog  
LOAEL: 3 - 30 mg/kg  
Application Route: Oral  
Exposure time: 6 Months  
Symptoms: Reduced body weight

**Aspiration toxicity**  
Not classified based on available information.
Experience with human exposure

Components:
mianserin hydrochloride:
Inhalation : Remarks: May be harmful if inhaled.
May cause irritation of respiratory tract.
Skin contact : Remarks: Can be absorbed through skin.
May irritate skin.
Eye contact : Remarks: May irritate eyes.
Ingestion : Symptoms: central nervous system effects, dry mouth, constipation, Headache, Tremors

12. ECOLOGICAL INFORMATION

Ecotoxicity
No data available

Persistence and degradability
No data available

Bioaccumulative potential

Components:
mianserin hydrochloride:
Partition coefficient: n-octanol/water : log Pow: 3.36
Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
GB 6944/12268
Not regulated as a dangerous good

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

The components of this product are reported in the following inventories:

AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Con-
centration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer
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