

# SAFETY DATA SHEET



## Mianserin Formulation



Version 2.8      Revision Date: 30.09.2023      SDS Number: 1601088-00012      Date of last issue: 04.04.2023  
Date of first issue: 01.05.2017

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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Mianserin Formulation

#### Manufacturer or supplier's details

Company name of supplier : Organon & Co.  
Address : Avenida 16 de Septiembre No. 301  
Xaltocan - Xochimilco Mexico 16090  
Telephone : +52 55 57284444  
Emergency telephone : 1-215-631-6999  
E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Reproductive toxicity : Category 2  
Specific target organ toxicity - single exposure : Category 1 (Central nervous system)

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.  
H370 Causes damage to organs (Central nervous system).

Precautionary Statements :

#### Prevention:

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/ vapors/ spray.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### Response:

P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.

#### Storage:

P405 Store locked up.

# SAFETY DATA SHEET



## Mianserin Formulation



Version 2.8      Revision Date: 30.09.2023      SDS Number: 1601088-00012      Date of last issue: 04.04.2023  
Date of first issue: 01.05.2017

### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
mianserin hydrochloride	21535-47-7	>= 10 -< 20
Starch	9005-25-8	>= 10 -< 20

## SECTION 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.  
Thoroughly clean shoes before reuse.
- In case of eye contact : 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.

## SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.

# SAFETY DATA SHEET



## Mianserin Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.8	30.09.2023	1601088-00012	Date of first issue: 01.05.2017

---

- Specific hazards during fire fighting : 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
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 : Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air.  
Add excess liquid to allow the material to enter into solution.  
Soak up with inert absorbent material.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal 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.
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### SECTION 7. HANDLING AND STORAGE

- 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 breathe dust, fume, gas, mist, vapors or spray.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
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# SAFETY DATA SHEET



## Mianserin Formulation



Version 2.8      Revision Date: 30.09.2023      SDS Number: 1601088-00012      Date of last issue: 04.04.2023  
Date of first issue: 01.05.2017

- Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- 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.
- Conditions for safe storage : Keep in properly labeled 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  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
mianserin hydrochloride	21535-47-7	TWA	20 µg/m <sup>3</sup> (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	200 µg/100 cm <sup>2</sup>	Internal
Starch	9005-25-8	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010-STPS-2014
		TWA	10 mg/m <sup>3</sup>	ACGIH

- 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

#### Hand protection

- Material : Chemical-resistant gloves

- Remarks : Choose gloves to protect hands against chemicals depending on the concentration 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. Wash hands before breaks and at the end of workday.

- Eye protection : Wear the following personal protective equipment:  
Safety glasses

- Skin and body protection : Select appropriate protective clothing based on chemical

# SAFETY DATA SHEET



## Mianserin Formulation



Version 2.8      Revision Date: 30.09.2023      SDS Number: 1601088-00012      Date of last issue: 04.04.2023  
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---

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

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Crystalline solid
Color	:	white to off-white
Odor	:	No data available
Odor 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
Vapor pressure	:	No data available
Relative vapor 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
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	No data available

# SAFETY DATA SHEET



## Mianserin Formulation

Version 2.8      Revision Date: 30.09.2023      SDS Number: 1601088-00012      Date of last issue: 04.04.2023  
Date of first issue: 01.05.2017

---

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : Not applicable

Particle size : No data available

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### SECTION 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.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

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

#### 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 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

---

# SAFETY DATA SHEET



## Mianserin Formulation

Version 2.8      Revision Date: 30.09.2023      SDS Number: 1601088-00012      Date of last issue: 04.04.2023  
Date of first issue: 01.05.2017

---

### **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.

#### **Starch:**

Species : Rabbit  
Result : No eye irritation

### **Respiratory or skin sensitization**

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

Not classified based on available information.

#### **Components:**

##### **mianserin hydrochloride:**

Remarks : Not classified due to lack of data.

#### **Starch:**

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

### **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)  
Result: negative

Remarks: Based on data from similar materials

Test Type: sister chromatid exchange assay

# SAFETY DATA SHEET



## Mianserin Formulation



Version 2.8      Revision Date: 30.09.2023      SDS Number: 1601088-00012      Date of last issue: 04.04.2023  
Date of first issue: 01.05.2017

---

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

### Starch:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

### 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 fetal development : Test Type: Development  
Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 10 mg/kg body weight  
Result: Effects on postnatal development.



# SAFETY DATA SHEET



## Mianserin Formulation



Version 2.8      Revision Date: 30.09.2023      SDS Number: 1601088-00012      Date of last issue: 04.04.2023  
Date of first issue: 01.05.2017

---

Test Type: Development  
Species: Rat  
Developmental Toxicity: LOAEL: 3 mg/kg body weight  
Result: Embryo-lethal effects., No teratogenic effects.

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

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

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

### STOT-single exposure

Causes damage to organs (Central nervous system).

#### 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

##### Starch:

Species : Rat  
NOAEL : >= 2,000 mg/kg  
Application Route : Skin contact  
Exposure time : 28 Days  
Method : OECD Test Guideline 410

# SAFETY DATA SHEET



## Mianserin Formulation

Version 2.8      Revision Date: 30.09.2023      SDS Number: 1601088-00012      Date of last issue: 04.04.2023  
Date of first issue: 01.05.2017

---

### 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

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## SECTION 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

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
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.

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

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# SAFETY DATA SHEET



## Mianserin Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.8	30.09.2023	1601088-00012	Date of first issue: 01.05.2017

---

### 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.

### Domestic regulation

#### NOM-002-SCT

Not regulated as a dangerous good

#### Special precautions for user

Not applicable

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## SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

### The ingredients of this product are reported in the following inventories:

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

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## SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023  
Date format : dd.mm.yyyy

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits  
ACGIH / TWA : 8-hour, time-weighted average  
NOM-010-STPS-2014 / VLE- : Time weighted average limit value  
PPT

AIIC - Australian Inventory of Industrial Chemicals; 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

# SAFETY DATA SHEET



## Mianserin Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.8	30.09.2023	1601088-00012	Date of first issue: 01.05.2017

---

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 Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration 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; TECl - Thailand Existing Chemicals Inventory; 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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