SAFETY DATA SHEET

Mianserin Formulation

Version 2.2  Revision Date: 09/13/2019  SDS Number: 1601118-00006  Date of last issue: 04/24/2019

Date of first issue: 05/01/2017

SECTION 1. IDENTIFICATION

Product name: Mianserin Formulation
Other means of identification: No data available

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

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Reproductive toxicity: Category 2
Specific target organ toxicity: Category 1 (Central nervous system)
- single exposure

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.
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>mianserin hydrochloride</td>
<td>21535-47-7</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
</tbody>
</table>

Actual concentration or concentration range is withheld as a trade secret.

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.

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 (CO2)
Dry chemical

Unsuitable extinguishing media: None known.
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<thead>
<tr>
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</tr>
</tbody>
</table>

media
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 fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 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 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.

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 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.
Conditions for safe storage: Keep in properly labeled containers. Store locked up. Store in accordance with the particular national regulations.
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Materials to avoid:
Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>
</tbody>
</table>

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

Starch
- TWA 10 mg/m³ CA AB OEL
- TWAEV (total dust) 10 mg/m³ CA QC OEL
- TWA (Total dust) 10 mg/m³ CA BC OEL
- TWA (respirable dust fraction) 3 mg/m³ CA BC OEL
- TWA 10 mg/m³ ACGIH

Engineering measures:
Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m³ - total dust, 5 mg/m³ - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m³ - respirable particles, 10 mg/m³ - inhalable particles.

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

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.

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
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
Possible hazardous decomposition products: No hazardous decomposition products are known.

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
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**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 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.

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

**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

**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

SECTION 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.

SECTION 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.

Domestic regulation

TDG
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined
SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA QC OEL / TWAEV : Time-weighted average exposure value

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 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; 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


Revision Date : 09/13/2019
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

CA / Z8