SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Mianserin Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Mianserin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company: MSD
Innishannon
County Cork - Ireland

Telephone: 353 214329300
Telefax: 908-735-1496
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Reproductive toxicity, Category 2
Specific target organ toxicity - single exposure, Category 1

H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.
H370: Causes damage to organs.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms: 

Signal word: Danger

Hazard statements: H361fd Suspected of damaging fertility. Suspected of damaging the unborn child. H370 Causes damage to organs.

Precautionary statements: Prevention:
Mianserin Formulation

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Date of last issue: 24.04.2019
Date of first issue: 01.05.2017

P201 Obtain special instructions before use.
P260 Do not breathe dust.
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.

Hazardous components which must be listed on the label:
mianserin hydrochloride

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>mianserin hydrochloride</td>
<td>21535-47-7 244-426-7</td>
<td>Acute Tox. 4; H302 Repr. 2; H361Fd STOT SE 1; H370</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
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<tbody>
<tr>
<td>2.2</td>
<td>09/13/2019</td>
<td>1609316-00006</td>
<td>24.04.2019</td>
<td>01.05.2017</td>
</tr>
</tbody>
</table>

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.

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

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

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

**Treatment**
- Treat symptomatically and supportively.

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

**Suitable extinguishing media**
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

**Unsuitable extinguishing media**
- None known.

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

**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

#### 5.3 Advice for firefighters

**Special protective equipment for firefighters**
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

**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.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
Advice on common storage  : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)
Specific use(s)  : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>OELV - 8 hrs (TWA) (Respirable dust)</td>
<td>4 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>OELV - 8 hrs (TWA) (inhalable dust)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
<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>Further information</td>
<td>Skin</td>
<td>Wipe limit</td>
<td>200 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Silica</td>
<td>71187-19-4</td>
<td>OELV - 8 hrs (TWA) (Respirable dust)</td>
<td>2.4 mg/m³ (Silica)</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>OELV - 8 hrs (TWA) (inhalable dust)</td>
<td>6 mg/m³ (Silica)</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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

Personal protective equipment
Eye protection  : Wear the following personal protective equipment:
Safety glasses
Equipment should conform to I.S. EN 166
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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. Wash hands before breaks and at the end of workday.

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).

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 (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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
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.

9.2 Other information
- Flammability (liquids): No data available
- Molecular weight: Not applicable
- Particle size: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure:
- Skin contact
- Ingestion
- Eye contact
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Acute toxicity
Not classified based on available information.

**Product:**
Acute oral toxicity: Acute toxicity estimate: > 2,000 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

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
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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 foetal development:
Test Type: Development
Species: Rat
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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 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

SECTION 12: Ecological information

12.1 Toxicity
No data available

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential

Components:

mianserin hydrochloride:
Partition coefficient: n-octanol/water  :  log Pow: 3.36

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product  :  Dispose of in accordance with local regulations.  
         :  According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.  
         :  Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
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

14.1 UN number
Not regulated as a dangerous good
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Date of first issue: 01.05.2017

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants: Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable


<table>
<thead>
<tr>
<th>H3</th>
<th>STOT SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quantity 1: 50 t</td>
</tr>
<tr>
<td></td>
<td>Quantity 2: 200 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS: not determined
DSL: not determined
IECSC: not determined
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15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-statements
H302 : Harmful if swallowed.
H361fd : Suspected of damaging fertility. Suspected of damaging the unborn child.
H370 : Causes damage to organs.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Repr. : Reproductive toxicity
STOT SE : Specific target organ toxicity - single exposure
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxin; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; IECSL - 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; KECL - 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature;
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SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repr. 2 H361fd Calculation method</td>
</tr>
<tr>
<td>STOT SE 1 H370 Calculation method</td>
</tr>
</tbody>
</table>

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.

IE / EN