Mianserin Formulation



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 Revision Date:
 SDS Number:
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 13.09.2019
 1601088-00006
 Date of first issue: 01.05.2017

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 : 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

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.

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.

Disposal:





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P501 Dispose of contents/ container to an approved waste dis-

posal 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

In the case of accident or if you feel unwell, seek medical General advice

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. Flush eyes with water as a precaution.

In case of eye contact

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. Suspected of damaging fertility. Suspected of damaging the

Most important symptoms and effects, both acute and

unborn child.

Causes damage to organs.

Protection of first-aiders

Notes to physician

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).

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

delayed

None known.

Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health.

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Hazardous combustion prod-

ucts

Carbon oxides Metal oxides

Oxides of phosphorus

Silicon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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, protec- : tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice and personal protective

equipment recommendations.

Discharge into the environment must be avoided. **Environmental precautions**

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.

Do not swallow. Advice on safe handling

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.

If exposure to chemical is likely during typical use, provide eye Hygiene measures

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.





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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 Organic peroxides

Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis	
		(Form of	ters / Permissible		
		exposure)	concentration		
mianserin hydrochloride	21535-47-7	TWA	20 μg/m3 (OEB 3)	Internal	
	Further information: Skin				
		Wipe limit	200 μg/100 cm ²	Internal	
Starch	9005-25-8	VLE-PPT	10 mg/m ³	NOM-010-	
				STPS-2014	
		TWA	10 mg/m³	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 Hand protection Particulates type

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).

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Crystalline solid

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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

nt and boiling : 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

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

Not classified as a reactivity hazard. Reactivity Stable under normal conditions. Chemical stability Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

Conditions to avoid None known. Incompatible materials Oxidizing agents

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 toxicity estimate: > 5,000 mg/kg Acute oral toxicity

Method: Calculation method

Components:

mianserin hydrochloride:

Acute oral toxicity LD50 (Rat): 780 mg/kg

LD50 (Mouse): 224 mg/kg

administration)

Acute toxicity (other routes of : LD50 (Mouse): 32 mg/kg Application Route: Intravenous

Starch:

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

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.

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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.

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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 - As-

sessment

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.



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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, consti-

pation, Headache, Tremors

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

Components:

mianserin hydrochloride:

Partition coefficient: n-

: log Pow: 3.36

octanol/water

Mobility in soilNo data available

Other adverse effects

No data available

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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste Contaminated packaging

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

NOM-002-SCT

Not regulated as a dangerous good

Special precautions for user

Not applicable

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

SECTION 16. OTHER INFORMATION

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





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the Work Environment - Identification, Assessment and Con-

trol - Appendix 1 Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average NOM-010-STPS-2014 / VLE- : Time weighted average limit value

PPT

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

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 Agen-

cy, http://echa.europa.eu/

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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.

MX / Z8