

# SAFETY DATA SHEET



## Asenapine Formulation



Version 3.4      Revision Date: 10.10.2020      SDS Number: 690797-00012      Date of last issue: 23.03.2020  
Date of first issue: 19.05.2016

---

### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Asenapine 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

Acute toxicity (Oral) : Category 3  
Acute toxicity (Inhalation) : Category 4  
Reproductive toxicity : Category 2  
Specific target organ toxicity - single exposure (Oral) : Category 1 (Central nervous system, Cardio-vascular system)  
Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Central nervous system)

#### GHS label elements

Hazard pictograms :  

Signal Word : Danger

Hazard Statements : H301 Toxic if swallowed.  
H332 Harmful if inhaled.  
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.  
H370 Causes damage to organs (Central nervous system, Cardio-vascular system) if swallowed.  
H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

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.

## Asenapine Formulation

Version 3.4      Revision Date: 10.10.2020      SDS Number: 690797-00012      Date of last issue: 23.03.2020  
Date of first issue: 19.05.2016

P270 Do not eat, drink or smoke when using this product.  
P271 Use only outdoors or in a well-ventilated area.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician. Rinse mouth.  
P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell.  
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards**

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate	85650-56-2	>= 30 -< 50

**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.  
If not breathing, give artificial respiration.  
If breathing is difficult, give oxygen.  
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 : If in eyes, rinse well with water.

## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	690797-00012	Date of first issue: 19.05.2016

---

If swallowed	:	Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Call a physician or poison control center immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	:	Toxic if swallowed. Harmful if inhaled. Suspected of damaging fertility. Suspected of damaging the unborn child. Causes damage to organs if swallowed. Causes damage to organs through prolonged or repeated exposure if swallowed. Contact with dust can cause mechanical irritation or drying of the skin.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. 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.
Specific hazards during fire fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NO <sub>x</sub> )
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 (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

## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	690797-00012	Date of first issue: 19.05.2016

---

cannot be contained.

Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
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 : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not breathe dust.  
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  
Keep container tightly closed.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
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.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.

# SAFETY DATA SHEET



## Asenapine Formulation



Version 3.4      Revision Date: 10.10.2020      SDS Number: 690797-00012      Date of last issue: 23.03.2020  
Date of first issue: 19.05.2016

Materials to avoid : Store in accordance with the particular national regulations.  
: 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 (Form of exposure)	Control parameters / Permissible concentration	Basis
trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate	85650-56-2	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm <sup>2</sup>	Internal

**Engineering measures** : Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Essentially no open handling permitted.  
Use closed processing systems or containment technologies.

#### 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 : Consider double gloving.  
Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.  
Skin and body protection : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

# SAFETY DATA SHEET



## Asenapine Formulation



Version 3.4      Revision Date: 10.10.2020      SDS Number: 690797-00012      Date of last issue: 23.03.2020  
Date of first issue: 19.05.2016

---

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	white to off-white
Odor	:	odorless
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	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
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	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive

# SAFETY DATA SHEET



## Asenapine Formulation



Version 3.4      Revision Date: 10.10.2020      SDS Number: 690797-00012      Date of last issue: 23.03.2020  
Date of first issue: 19.05.2016

---

Oxidizing properties : The substance or mixture is not classified as oxidizing.  
Particle size : 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 : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.  
Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

---

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Toxic if swallowed.  
Harmful if inhaled.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 238.4 mg/kg  
Method: Calculation method  
Acute inhalation toxicity : Acute toxicity estimate: 1.08 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

#### Components:

#### **trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:**

Acute oral toxicity : LD50 (Rat): 110 - 178 mg/kg  
LD50 (Dog): > 200 mg/kg  
Remarks: No mortality observed at this dose.  
Acute inhalation toxicity : LC50 (Rat): 0.5 - 2 mg/l  
Exposure time: 1 h  
Test atmosphere: dust/mist  
Acute toxicity (other routes of administration) : LD50 (Rat): > 200 mg/kg  
Application Route: Intravenous

---

## Asenapine Formulation

Version 3.4      Revision Date: 10.10.2020      SDS Number: 690797-00012      Date of last issue: 23.03.2020  
Date of first issue: 19.05.2016

---

Target Organs: Central nervous system  
Remarks: No mortality observed at this dose.

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole ma-  
leate:**

Remarks : No data available

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole ma-  
leate:**

Remarks : No data available

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:**

**trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole ma-  
leate:**

Species : Guinea pig  
Result : Not a skin sensitizer.

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole ma-  
leate:**

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

Test Type: Mouse Lymphoma  
Result: negative

Test Type: sister chromatid exchange assay  
Result: negative

Test Type: Chromosomal aberration  
Test system: Human lymphocytes



## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	690797-00012	Date of first issue: 19.05.2016

---

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Rat  
Application Route: Oral  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:**

Species : Mouse  
Application Route : Subcutaneous  
Exposure time : 89 - 98 weeks  
Result : negative

Species : Rat  
Application Route : Subcutaneous  
Exposure time : 100 - 106 weeks  
Result : negative

**Reproductive toxicity**

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

**Components:****trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 1.0 mg/kg body weight  
Symptoms: Reduced maternal body weight gain., Reduced offspring weight gain., Effects on fertility., Effects on F1 offspring.  
Result: Embryotoxic effects and adverse effects on the offspring were detected.

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 30 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Intravenous injection  
Developmental Toxicity: NOAEL: 0.626 mg/kg body weight  
Result: No teratogenic effects.

## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	690797-00012	Date of first issue: 19.05.2016

---

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

**STOT-single exposure**

Causes damage to organs (Central nervous system, Cardio-vascular system) if swallowed.

**Components:****trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:**

Routes of exposure : Oral  
 Target Organs : Central nervous system, Cardio-vascular system  
 Assessment : Causes damage to organs.

**STOT-repeated exposure**

Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

**Components:****trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:**

Routes of exposure : Ingestion  
 Target Organs : Central nervous system  
 Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:**

Species : Rat  
 LOAEL : 0.6 mg/kg  
 Application Route : Oral  
 Exposure time : 52 Weeks  
 Target Organs : Central nervous system  
 Symptoms : constriction of pupils

Species : Rat  
 LOAEL : 0.1 mg/kg  
 Application Route : Intravenous  
 Exposure time : 14 Weeks  
 Symptoms : constriction of pupils, Lachrymation

Species : Rat  
 LOAEL : 0.5 mg/kg  
 Application Route : Subcutaneous  
 Exposure time : 13 Weeks  
 Target Organs : Central nervous system

## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	690797-00012	Date of first issue: 19.05.2016

---

Species	:	Dog
LOAEL	:	> 1.25 mg/kg
Application Route	:	Oral
Exposure time	:	13 - 52 Weeks
Target Organs	:	Central nervous system
Symptoms	:	constriction of pupils, Tremors, Irritability

**Aspiration toxicity**

Not classified based on available information.

**Components:****trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole ma-  
leate:**

Not applicable

**Experience with human exposure****Components:****trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole ma-  
leate:**

Ingestion	:	Symptoms: restlessness, Drowsiness, Dizziness, decrease in heart rate, hypotension
-----------	---	------------------------------------------------------------------------------------

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole ma-  
leate:**

Toxicity to fish	:	LC50 (Cyprinus carpio (Carp)): 0.53 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 0.27 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  NOEC (Pseudokirchneriella subcapitata (green algae)): 0.084 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 0.04 mg/l Exposure time: 21 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.00086 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	690797-00012	Date of first issue: 19.05.2016

---

Toxicity to microorganisms : EC50: 37 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC: 10 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**Persistence and degradability**

No data available

**Bioaccumulative potential****Components:****trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:**

Bioaccumulation : Species: Cyprinus carpio (Carp)  
Bioconcentration factor (BCF): 2,424

Partition coefficient: n-octanol/water : log Pow: 4.9

**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**

UN number : UN 2811  
Proper shipping name : TOXIC SOLID, ORGANIC, N.O.S.  
(trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate)  
Class : 6.1  
Packing group : III  
Labels : 6.1

**IATA-DGR**

UN/ID No. : UN 2811

## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	690797-00012	Date of first issue: 19.05.2016

---

Proper shipping name : Toxic solid, organic, n.o.s.  
(trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate)

Class : 6.1

Packing group : III

Labels : Toxic

Packing instruction (cargo aircraft) : 677

Packing instruction (passenger aircraft) : 670

**IMDG-Code**

UN number : UN 2811

Proper shipping name : TOXIC SOLID, ORGANIC, N.O.S.  
(trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate)

Class : 6.1

Packing group : III

Labels : 6.1

EmS Code : F-A, S-A

Marine pollutant : yes

**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**

UN number : UN 2811

Proper shipping name : TOXIC SOLID, ORGANIC, N.O.S.  
(trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate)

Class : 6.1

Packing group : III

Labels : 6.1

**Special precautions for user**

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

**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

## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.4	10.10.2020	690797-00012	Date of first issue: 19.05.2016

---

IECSC : not determined

---

**SECTION 16. OTHER INFORMATION****Full text of other abbreviations**

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 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; 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; 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 Agency, <http://echa.europa.eu/>

Revision Date : 10.10.2020

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