# **Asenapine Formulation**



Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.0 30.09.2023 691116-00017 Date of first issue: 19.05.2016

#### **SECTION 1. IDENTIFICATION**

Product name : Asenapine Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor

Jersey City, New Jersey, U.S.A 07302

Telephone : 1-551-430-6000

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

#### **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)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

**GHS** label elements

Hazard pictograms :







Signal Word : Danger





 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.0
 30.09.2023
 691116-00017
 Date of first issue: 19.05.2016

Hazard Statements : H301 Toxic if swallowed.

H332 Harmful if inhaled.

H361fd Suspected of damaging fertility. Suspected of damag-

ing 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. H410 Very toxic to aquatic life with long lasting effects.

**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.

P271 Use only outdoors or in a well-ventilated area.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

#### Response:

P301 + P310 + P330 IF SWALLOWED: Immediately call a

POISON CENTER/ doctor. Rinse mouth.

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/

doctor if you feel unwell.

P308 + P311 IF exposed or concerned: Call a POISON

CENTER/ doctor. P391 Collect spillage.

### Storage:

P405 Store locked up.

#### Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

### Other hazards which do not result in classification

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 male-	85650-56-2	>= 30 -< 50
ate		

# **Asenapine Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.0
 30.09.2023
 691116-00017
 Date of first issue: 19.05.2016

**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.

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.

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 (CO2)

Dry chemical

Unsuitable extinguishing

Protection of first-aiders

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 prod-

ucts

Carbon oxides

Nitrogen oxides (NOx)

# **Asenapine Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.0
 30.09.2023
 691116-00017
 Date of first issue: 19.05.2016

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, 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.

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. 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.

#### **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



## **Asenapine Formulation**



Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.0 30.09.2023 691116-00017 Date of first issue: 19.05.2016

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.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up. Keep tightly closed.

Keep in a cool, well-ventilated place.

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		
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/m3 (OEB 4)	Internal		
	Further inform	Further information: Skin				
		Wipe limit	10 μg/100 cm <sup>2</sup>	Internal		

**Engineering measures** : Containment to

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

Hand protection

Particulates type





 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.0
 30.09.2023
 691116-00017
 Date of first issue: 19.05.2016

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.

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.

### **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





 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.0
 30.09.2023
 691116-00017
 Date of first issue: 19.05.2016

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

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 reac-

tions

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

Hazardous decomposition

: Oxidizing agents

No hazardous decomposition products are known.

**SECTION 11. TOXICOLOGICAL INFORMATION** 

Information on likely routes of :

exposure

products

Inhalation Skin contact Ingestion

Ingestion Eye contact

**Acute toxicity** 

Toxic if swallowed. Harmful if inhaled.

# **Asenapine Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.0
 30.09.2023
 691116-00017
 Date of first issue: 19.05.2016

**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

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 maleate:

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 maleate:

Remarks : No data available

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

# **Asenapine Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.0
 30.09.2023
 691116-00017
 Date of first issue: 19.05.2016

#### 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 maleate:

Test Type: Mouse Lymphoma

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

ŭ

Result: negative

Test Type: sister chromatid exchange assay

Result: negative

Test Type: Chromosomal aberration Test system: Human lymphocytes

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.

# **Asenapine Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.0
 30.09.2023
 691116-00017
 Date of first issue: 19.05.2016

#### **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 off-

spring

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.

Reproductive toxicity - As-

sessment

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

# **Asenapine Formulation**



Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.0 30.09.2023 691116-00017 Date of first issue: 19.05.2016

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

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 maleate:

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 maleate:

Ingestion : Symptoms: restlessness, Drowsiness, Dizziness, decrease in

heart rate, hypotension

# **Asenapine Formulation**



 Version
 Revision Date:
 SDS Number:
 D

 4.0
 30.09.2023
 691116-00017
 D

Date of last issue: 04.04.2023 Date of first issue: 19.05.2016

#### **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 maleate:

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): 0,53 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to algae/aquatic : 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

M-Factor (Acute aquatic tox- : 1

city)

plants

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 0,04 mg/l

Exposure time: 21 d

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0,00086 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

100

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



### **Asenapine Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.0
 30.09.2023
 691116-00017
 Date of first issue: 19.05.2016

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 : 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.

#### **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
Environmentally hazardous : yes

**IATA-DGR** 

UN/ID No. : 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 : Toxic
Packing instruction (cargo : 677

aircraft)

Packing instruction (passen: 670

ger aircraft)

**IMDG-Code** 

UN number : UN 2811

Proper shipping name : TOXIC SOLID, ORGANIC, N.O.S.

 $(trans\hbox{-}5\hbox{-}Chloro\hbox{-}2,3,3a,12b\hbox{-}tetrahydro\hbox{-}2\hbox{-}methyl\hbox{-}1H\hbox{-}$ 

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

# **Asenapine Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.0
 30.09.2023
 691116-00017
 Date of first issue: 19.05.2016

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### 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

Argentina. Carcinogenic Substances and Agents

Not applicable

Registry.

Control of precursors and essential chemicals for the

Not applicable

preparation of drugs.

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

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

**Further information** 

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 Agentus http://ach.gov.nag.gov/

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

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 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

# Public



# **Asenapine Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.0
 30.09.2023
 691116-00017
 Date of first issue: 19.05.2016

- 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; TECI - 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

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.

AR / Z8