according to the Globally Harmonized System



# **Asenapine Formulation**

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

 4.0
 30.09.2023
 691128-00017
 Date of first issue: 19.05.2016

#### 1. PRODUCT AND COMPANY 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 number: +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

# 2. HAZARDS IDENTIFICATION

## Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

#### Classification

Toxic

**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

according to the Globally Harmonized System



# **Asenapine Formulation**

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

 4.0
 30.09.2023
 691128-00017
 Date of first issue: 19.05.2016

Hazard pictograms :







Signal word : Danger

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:

P203 Obtain, read and follow all safety 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. 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 + P316 + P330 IF SWALLOWED: Get emergency medi-

cal help immediately. Rinse mouth.

P304 + P340 + P317 IF INHALED: Remove person to fresh air

and keep comfortable for breathing. Get medical help.

P308 + P316 IF exposed or concerned: Get emergency medi-

cal help immediately. 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.

# 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

according to the Globally Harmonized System



# **Asenapine Formulation**

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

 4.0
 30.09.2023
 691128-00017
 Date of first issue: 19.05.2016

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

4. FIRST AID MEASURES

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

vice 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 centre 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

he 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).

: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Notes to physician

Protection of first-aiders

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

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.

according to the Globally Harmonized System



# **Asenapine Formulation**

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.0 30.09.2023 691128-00017 Date of first issue: 19.05.2016

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

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 firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emergency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 minimise 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 absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

# 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.

according to the Globally Harmonized System



# **Asenapine Formulation**

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

 4.0
 30.09.2023
 691128-00017
 Date of first issue: 19.05.2016

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 as-

sessment

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 labelled 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:

**Explosives** 

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Components 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 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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection Particulates type

according to the Globally Harmonized System



# **Asenapine Formulation**

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

 4.0
 30.09.2023
 691128-00017
 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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : white to off-white

Odour : odourless

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 : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

according to the Globally Harmonized System



# **Asenapine Formulation**

**Revision Date:** Date of last issue: 04.04.2023 Version SDS Number: 4.0 30.09.2023 691128-00017 Date of first issue: 19.05.2016

Lower explosion limit / Lower :

flammability limit

No data available

Vapour pressure Not applicable

Relative vapour 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

Auto-ignition temperature No data available

Decomposition temperature No data available

Viscosity

Not applicable Viscosity, kinematic

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

Particle size No data available

## 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, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks.

Avoid dust formation. Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

# 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion Eye contact

according to the Globally Harmonized System



# **Asenapine Formulation**

Date of last issue: 04.04.2023 **Revision Date:** Version SDS Number: 4.0 30.09.2023 691128-00017 Date of first issue: 19.05.2016

#### **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 ma-

: LD50 (Rat): 110 - 178 mg/kg Acute oral toxicity

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 :

LD50 (Rat): > 200 mg/kg

Application Route: Intravenous administration)

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 sensitisation

# Skin sensitisation

Not classified based on available information.

according to the Globally Harmonized System



# **Asenapine Formulation**

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

 4.0
 30.09.2023
 691128-00017
 Date of first issue: 19.05.2016

#### Respiratory sensitisation

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 : 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:

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

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

according to the Globally Harmonized System



# **Asenapine Formulation**

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

 4.0
 30.09.2023
 691128-00017
 Date of first issue: 19.05.2016

#### 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 off-

spring

Result: Embryotoxic effects and adverse effects on the off-

spring were detected.

Effects on foetal develop-

ment

Test Type: Embryo-foetal 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-foetal 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 experi-

ments.

## 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:

Exposure routes : 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.

according to the Globally Harmonized System



# **Asenapine Formulation**

**Revision Date:** Date of last issue: 04.04.2023 Version SDS Number: 4.0 30.09.2023 691128-00017 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-

Exposure routes Ingestion

Target Organs Central nervous system

: Causes damage to organs through prolonged or repeated Assessment

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 : 52 Weeks Exposure time

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
Exposure time Subcutaneous Exposure time : 13 Weeks

Target Organs Central nervous system

Species Dog

LOAEL : > 1.25 mg/kg

Application Route
Exposure time Oral

: 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

according to the Globally Harmonized System



# **Asenapine Formulation**

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.0 30.09.2023 691128-00017 Date of first issue: 19.05.2016

#### **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

#### 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-

icity)

plants

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

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.04 mg/l Exposure time: 21 d

Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.00086 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

M-Factor (Chronic aquatic : 100

according to the Globally Harmonized System



# **Asenapine Formulation**

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

 4.0
 30.09.2023
 691128-00017
 Date of first issue: 19.05.2016

toxicity)

Persistence and degradability

No data available

**Bioaccumulative potential** 

**Components:** 

 $trans-5-Chloro-2, 3, 3a, 12b-tetrahydro-2-methyl-1 H-dibenz [2, 3:6, 7] oxepino [4, 5-c] pyrrole\ manual and the sum of the context of the$ 

leate:

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

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

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

according to the Globally Harmonized System



# **Asenapine Formulation**

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

 4.0
 30.09.2023
 691128-00017
 Date of first issue: 19.05.2016

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-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 IMO instruments

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.

## 15. REGULATORY INFORMATION

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### 16. OTHER INFORMATION

Revision Date : 30.09.2023

**Further information** 

Sources of key data used to compile the Safety Data

compile the 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/

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

Date format : dd.mm.yyyy

according to the Globally Harmonized System



# **Asenapine Formulation**

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

 4.0
 30.09.2023
 691128-00017
 Date of first issue: 19.05.2016

#### 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; 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.

IN / EN