

# SAFETY DATA SHEET



## Asenapine Formulation



Version 2.1      Revision Date: 2020/10/10      SDS Number: 690795-00011      Date of last issue: 2020/03/23  
Date of first issue: 2016/05/19

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Asenapine Formulation

#### Supplier's company name, address and phone number

Company name of supplier : Organon & Co.

Address : 30 Hudson Street, 33nd floor  
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : 215-631-6999

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

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### 2. HAZARDS IDENTIFICATION

#### GHS classification of chemical product

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

Hazard statements : H301 Toxic if swallowed.  
H332 Harmful if inhaled.  
H361fd Suspected of damaging fertility. Suspected of damag-

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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 protection/ 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

Important symptoms and out- : Dust contact with the eyes can lead to mechanical irritation.  
lines of the emergency as- Contact with dust can cause mechanical irritation or drying of  
sumed the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
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	>= 40 - < 50	

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**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 : 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 the skin.  
Dust contact with the eyes can lead to mechanical irritation.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

**5. FIREFIGHTING 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>)

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- 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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### 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 : 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.
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### 7. HANDLING AND STORAGE

#### Handling

- 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.
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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.

Avoidance of contact : Oxidizing agents  
 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.

**Storage**

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:  
 Strong oxidizing agents

Packaging material : Unsuitable material: None known.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Threshold limit value and permissible exposure limits for each component in the work environment**

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.

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### 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.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

Colour : white to off-white

Odour : odourless

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit  
Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : Not applicable

Decomposition temperature : No data available

pH : No data available

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Evaporation rate : Not applicable

Auto-ignition temperature : No data available

Viscosity  
Viscosity, kinematic : Not applicable

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : Not applicable

Density and / or relative density  
Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Explosive properties : Not explosive

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

Particle characteristics  
Particle size : No data available

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### 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.

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### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Toxic if swallowed.

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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  
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.

#### **Respiratory sensitisation**

Not classified based on available information.



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**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

**Reproductive toxicity**

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

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**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 foetal development : 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 - 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:**

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.

**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 : Ingestion  
 Target Organs : Central nervous system

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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

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**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 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
M-Factor (Acute aquatic toxicity)	:	1
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
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
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Partition coefficient: n-octanol/water : log Pow: 4.9

### Mobility in soil

No data available

### Hazardous to the ozone layer

Not applicable

### Other adverse effects

No data available

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## 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.

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## 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  
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

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Marine pollutant : yes

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

Not applicable for product as supplied.

### **National Regulations**

Refer to section 15 for specific national regulation.

### **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.

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## 15. REGULATORY INFORMATION

### **Related Regulations**

#### **Fire Service Law**

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

#### **Industrial Safety and Health Law**

#### **Harmful Substances Prohibited from Manufacture**

Not applicable

#### **Harmful Substances Required Permission for Manufacture**

Not applicable

#### **Substances Prevented From Impairment of Health**

Not applicable

#### **Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

#### **Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

#### **Substances Subject to be Notified Names**

Not applicable

#### **Substances Subject to be Indicated Names**

Not applicable

#### **Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

#### **Ordinance on Prevention of Lead Poisoning**

Not applicable

#### **Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

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**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Toxic and infectious substances (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

**Aviation Law**

Toxic and infectious substances (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**16. OTHER INFORMATION****Further information**

Sources of key data used to compile the Safety Data : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

# SAFETY DATA SHEET



## Asenapine Formulation



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### 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; 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

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