

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Asenapine Formulation

Version 2.5      Revision Date: 09.04.2021      SDS Number: 691126-00013      Date of last issue: 10.10.2020  
Date of first issue: 19.05.2016

---

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Asenapine Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Pharmaceutical

#### 1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.  
Shotton Lane  
NE23 3JU Cramlington NU - Great Britain

Telephone : 44 1 670 59 30 00

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

#### 1.4 Emergency telephone number

215-631-6999

---

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 3	H301: Toxic if swallowed.
Acute toxicity, Category 4	H332: Harmful if inhaled.
Reproductive toxicity, Category 2	H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.
Specific target organ toxicity - single exposure, Category 1	H370: Causes damage to organs.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Asenapine Formulation

Version 2.5      Revision Date: 09.04.2021      SDS Number: 691126-00013      Date of last issue: 10.10.2020  
Date of first issue: 19.05.2016

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.  
H372 Causes damage to organs through prolonged or repeated exposure.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P260 Do not breathe dust.  
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.  
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.  
P391 Collect spillage.

### Hazardous components which must be listed on the label:

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

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	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	85650-56-2 288-064-8	Acute Tox. 3; H301 Acute Tox. 3; H331 Repr. 2; H361fd STOT SE 1; H370 (Central nervous system, Cardiovascular system) STOT RE 1; H372 (Central nervous system)	>= 30 - < 50

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Asenapine Formulation

Version 2.5      Revision Date: 09.04.2021      SDS Number: 691126-00013      Date of last issue: 10.10.2020  
Date of first issue: 19.05.2016

		Aquatic Acute 1; H400 Aquatic Chronic 1; H410	
		M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 100	

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of 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.
- 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).
- 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.

#### 4.2 Most important symptoms and effects, both acute and delayed

- Risks : Toxic if swallowed.  
Harmful if inhaled.  
Suspected of damaging fertility. Suspected of damaging the unborn child.  
Causes damage to organs.  
Causes damage to organs through prolonged or repeated exposure.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	691126-00013	Date of first issue: 19.05.2016

---

Contact with dust can cause mechanical irritation or drying of the skin.

Dust contact with the eyes can lead to mechanical irritation.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

---

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

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>)

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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.

---

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.

---

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	691126-00013	Date of first issue: 19.05.2016

---

Local authorities should be advised if significant spillages cannot be contained.

### 6.3 Methods and material for containment and cleaning up

Methods for 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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

---

## SECTION 7: Handling and storage

### 7.1 Precautions for safe 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.  
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,

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Asenapine Formulation

Version 2.5      Revision Date: 09.04.2021      SDS Number: 691126-00013      Date of last issue: 10.10.2020  
Date of first issue: 19.05.2016

appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : 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.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Organic peroxides  
Explosives  
Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	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

### 8.2 Exposure controls

#### 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

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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	691126-00013	Date of first issue: 19.05.2016

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Equipment should conform to BS EN 143

Filter type : Particulates type (P)

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic 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, 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

Vapour pressure : Not applicable

Relative vapour density : Not applicable

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	691126-00013	Date of first issue: 19.05.2016

---

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		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

### 9.2 Other information

Particle size	:	No data available
---------------	---	-------------------

---

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
---------------------	---	--

### 10.4 Conditions to avoid

Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
---------------------	---	---

### 10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
--------------------	---	------------------

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

---

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of exposure	:	Inhalation Skin contact
--	---	----------------------------



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Asenapine Formulation

Version 2.5      Revision Date: 09.04.2021      SDS Number: 691126-00013      Date of last issue: 10.10.2020  
Date of first issue: 19.05.2016

---

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  
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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Asenapine Formulation

Version 2.5      Revision Date: 09.04.2021      SDS Number: 691126-00013      Date of last issue: 10.10.2020  
Date of first issue: 19.05.2016

---

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	691126-00013	Date of first issue: 19.05.2016

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 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.

#### 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 through prolonged or repeated exposure.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Asenapine Formulation

Version 2.5      Revision Date: 09.04.2021      SDS Number: 691126-00013      Date of last issue: 10.10.2020  
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:**

Exposure routes : 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

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	691126-00013	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

## SECTION 12: Ecological information

### 12.1 Toxicity

#### 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 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 toxicity) : NOEC: 0.04 mg/l  
Exposure time: 21 d  
Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.00086 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 100

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	691126-00013	Date of first issue: 19.05.2016

---

toxicity)

### 12.2 Persistence and degradability

No data available

### 12.3 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

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Other adverse effects

#### Product:

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

---

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

### 14.1 UN number

ADN : UN 2811

---

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Asenapine Formulation

Version 2.5      Revision Date: 09.04.2021      SDS Number: 691126-00013      Date of last issue: 10.10.2020  
Date of first issue: 19.05.2016

**ADR** : UN 2811  
**RID** : UN 2811  
**IMDG** : UN 2811  
**IATA** : UN 2811

### 14.2 UN proper shipping name

**ADN** : 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)  
**ADR** : 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)  
**RID** : 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)  
**IMDG** : 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)  
**IATA** : 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)

### 14.3 Transport hazard class(es)

**ADN** : 6.1  
**ADR** : 6.1  
**RID** : 6.1  
**IMDG** : 6.1  
**IATA** : 6.1

### 14.4 Packing group

**ADN**  
Packing group : III  
Classification Code : T2  
Hazard Identification Number : 60  
Labels : 6.1  
**ADR**  
Packing group : III  
Classification Code : T2  
Hazard Identification Number : 60  
Labels : 6.1  
Tunnel restriction code : (E)  
**RID**  
Packing group : III  
Classification Code : T2  
Hazard Identification Number : 60  
Labels : 6.1

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Asenapine Formulation

Version 2.5      Revision Date: 09.04.2021      SDS Number: 691126-00013      Date of last issue: 10.10.2020  
Date of first issue: 19.05.2016

---

### IMDG

Packing group : III  
Labels : 6.1  
EmS Code : F-A, S-A

### IATA (Cargo)

Packing instruction (cargo aircraft) : 677  
Packing instruction (LQ) : Y645  
Packing group : III  
Labels : Toxic

### IATA (Passenger)

Packing instruction (passenger aircraft) : 670  
Packing instruction (LQ) : Y645  
Packing group : III  
Labels : Toxic

## 14.5 Environmental hazards

### ADN

Environmentally hazardous : yes

### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

## 14.6 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.

## 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

---

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable  
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable  
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable  
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable  
Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Asenapine Formulation

Version 2.5      Revision Date: 09.04.2021      SDS Number: 691126-00013      Date of last issue: 10.10.2020  
Date of first issue: 19.05.2016

tants (recast)

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

		Quantity 1	Quantity 2
H3	STOT SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE	50 t	200 t
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS : not determined

DSL : not determined

IECSC : not determined

## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

Other information : 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 H-Statements

H301 : Toxic if swallowed.  
H331 : Toxic if inhaled.  
H361fd : Suspected of damaging fertility. Suspected of damaging the unborn child.  
H370 : Causes damage to organs if swallowed.  
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.  
H400 : Very toxic to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.

### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Aquatic Acute : Short-term (acute) aquatic hazard  
Aquatic Chronic : Long-term (chronic) aquatic hazard  
Repr. : Reproductive toxicity  
STOT RE : Specific target organ toxicity - repeated exposure  
STOT SE : Specific target organ toxicity - single exposure

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Asenapine Formulation

Version 2.5      Revision Date: 09.04.2021      SDS Number: 691126-00013      Date of last issue: 10.10.2020  
Date of first issue: 19.05.2016

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Acute Tox. 3	H301
Acute Tox. 4	H332
Repr. 2	H361fd
STOT SE 1	H370
STOT RE 1	H372
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.5	09.04.2021	691126-00013	Date of first issue: 19.05.2016

---

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.

GB / EN