

SAFETY DATA SHEET

according to the Hazardous Products Regulations



ORGANON

Asenapine Formulation

Version 4.0 Revision Date: 09/30/2023 SDS Number: 690786-00019 Date of last issue: 04/04/2023
Date of first issue: 05/19/2016

SECTION 1. IDENTIFICATION

Product name : Asenapine Formulation
Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33rd floor
Jersey City, New Jersey, U.S.A 07302
Telephone : 1-551-430-6000
Emergency telephone : 1-215-631-6999
E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use



Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

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

GHS label elements

Hazard pictograms :  

Signal Word : Danger

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Asenapine Formulation

Version 4.0 Revision Date: 09/30/2023 SDS Number: 690786-00019 Date of last issue: 04/04/2023
Date of first issue: 05/19/2016

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.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

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

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	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	No data available	85650-56-2	>= 30 - < 60 *

* Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.0	09/30/2023	690786-00019	Date of first issue: 05/19/2016

-
- | | | |
|---|---|--|
| 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 center immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person. |
| Most important symptoms and effects, both acute and delayed | : | Toxic if swallowed.
Harmful if inhaled.
Suspected of damaging fertility. Suspected of damaging the unborn child.
Causes damage to organs if swallowed.
Causes damage to organs through prolonged or repeated exposure if swallowed.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation. |
| 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. |

SECTION 5. FIRE-FIGHTING MEASURES

- | | | |
|---------------------------------------|---|---|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
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 _x) |
| 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 | : | In the event of fire, wear self-contained breathing apparatus. |

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.0	09/30/2023	690786-00019	Date of first issue: 05/19/2016

for fire-fighters Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air. Add excess liquid to allow the material to enter into solution. Soak up with inert absorbent material. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety 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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Asenapine Formulation

Version 4.0 Revision Date: 09/30/2023 SDS Number: 690786-00019 Date of last issue: 04/04/2023
Date of first issue: 05/19/2016

- Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate	85650-56-2	TWA	1 µg/m ³ (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm ²	Internal

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

Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



ORGANON

Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.0	09/30/2023	690786-00019	Date of first issue: 05/19/2016

Skin and body protection : Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
: Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : white to off-white

Odor : odorless

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : Not applicable

Evaporation rate : Not applicable

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

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : Not applicable

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.0	09/30/2023	690786-00019	Date of first issue: 05/19/2016

Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Toxic if swallowed.
Harmful if inhaled.

Product:

SAFETY DATA SHEET

according to the Hazardous Products Regulations



ORGANON

Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.0	09/30/2023	690786-00019	Date of first issue: 05/19/2016

Acute oral toxicity : Acute toxicity estimate: 238.4 mg/kg
Method: Calculation method

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

Components:

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

Acute oral toxicity : LD50 (Rat): 110 - 178 mg/kg
LD50 (Dog): > 200 mg/kg
Remarks: No mortality observed at this dose.

Acute inhalation toxicity : LC50 (Rat): 0.5 - 2 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist

Acute toxicity (other routes of administration) : LD50 (Rat): > 200 mg/kg
Application Route: Intravenous
Target Organs: Central nervous system
Remarks: No mortality observed at this dose.

Skin corrosion/irritation

Not classified based on available information.

Components:

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

Remarks : No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:

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

Remarks : No data available

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Asenapine Formulation

Version 4.0 Revision Date: 09/30/2023 SDS Number: 690786-00019 Date of last issue: 04/04/2023
Date of first issue: 05/19/2016

Components:

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

Species : Guinea pig
Result : Not a skin sensitizer.

Germ cell mutagenicity

Not classified based on available information.

Components:

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

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

Test Type: Mouse Lymphoma
Result: negative

Test Type: sister chromatid exchange assay
Result: negative

Test Type: Chromosomal aberration
Test system: Human lymphocytes
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 ma-
leate:**

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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



ORGANON

Asenapine Formulation

Version 4.0 Revision Date: 09/30/2023 SDS Number: 690786-00019 Date of last issue: 04/04/2023
Date of first issue: 05/19/2016

Components:

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

Effects on fertility	: Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Oral Fertility: LOAEL: 1.0 mg/kg body weight Symptoms: Reduced maternal body weight gain., Reduced offspring weight gain., Effects on fertility., Effects on F1 offspring. Result: Embryotoxic effects and adverse effects on the offspring were detected.
Effects on fetal development	: Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 30 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects. Test Type: Embryo-fetal development Species: Rabbit Application Route: Intravenous injection Developmental Toxicity: NOAEL: 0.626 mg/kg body weight Result: No teratogenic effects.
Reproductive toxicity - Assessment	: Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure

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

Components:

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

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

STOT-repeated exposure

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

Components:

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

Routes of exposure	: Ingestion
--------------------	-------------

SAFETY DATA SHEET

according to the Hazardous Products Regulations



ORGANON

Asenapine Formulation

Version 4.0 Revision Date: 09/30/2023 SDS Number: 690786-00019 Date of last issue: 04/04/2023
Date of first issue: 05/19/2016

|| 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

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Asenapine Formulation

Version 4.0 Revision Date: 09/30/2023 SDS Number: 690786-00019 Date of last issue: 04/04/2023
Date of first issue: 05/19/2016

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

Toxicity to fish	: LC50 (Cyprinus carpio (Carp)): 0.53 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): 0.27 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 0.084 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): 0.04 mg/l Exposure time: 21 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 0.00086 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	: EC50: 37 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 NOEC: 10 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

Persistence and degradability

No data available

Bioaccumulative potential

Components:

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

Bioaccumulation	: Species: Cyprinus carpio (Carp) Bioconcentration factor (BCF): 2,424
Partition coefficient: n-octanol/water	: log Pow: 4.9

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.0	09/30/2023	690786-00019	Date of first issue: 05/19/2016

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

- Waste from residues : Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
- Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

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

IATA-DGR

- UN/ID No. : UN 2811
- Proper shipping name : Toxic solid, organic, n.o.s.
(trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate)
- Class : 6.1
- Packing group : III
- Labels : Toxic
- Packing instruction (cargo aircraft) : 677
- Packing instruction (passenger aircraft) : 670

IMDG-Code

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



ORGANON

Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.0	09/30/2023	690786-00019	Date of first issue: 05/19/2016

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

Not applicable for product as supplied.

Domestic regulation

TDG

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
ERG Code	: 154
Marine pollutant	: yes(trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate)

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION

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

AICS	: not determined
DSL	: not determined
IECSC	: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median

SAFETY DATA SHEET

according to the Hazardous Products Regulations



ORGANON

Asenapine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
4.0	09/30/2023	690786-00019	Date of first issue: 05/19/2016

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; TECl - 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

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

Revision Date : 09/30/2023
Date format : mm/dd/yyyy

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

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.

CA / Z8