

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Asenapine Sublingual Tablets (Greenstone LLC)
Product Code(s) PF00006
Trade Name: Not established
Chemical Family: Dibenzoxepinopyrrole

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

Recommended Use Pharmaceutical product used as Psychopharmic antipsychotic

1.3. Details of the supplier of the safety data sheet

Greenstone LLC
100 Route 206 North
Peapack, NJ 07977
800-435-7095

1.4. Emergency telephone number

Emergency Telephone CHEMTREC (24 hours): 1-800-424-9300

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Reproductive toxicity Category 2 - H361d

2.2. Label elements

Signal word Danger
Hazard statements H361d - Suspected of damaging the unborn child
Precautionary Statements P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves and eye/face protection
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations



2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

SAFETY DATA SHEET

Product Name Asenapine Sublingual Tablets (Greenstone LLC)
Revision date 05-Mar-2020

Page 2 / 8
Version 1.01

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Hazardous

| Chemical Name | EC No | CAS No | Weight-% | Classification according to Regulation (EC) No. 1272/2008 [CLP] | REACH Registration Number |
|-------------------|-----------|------------|----------|---|---------------------------|
| Asenapine maleate | 288-064-8 | 85650-56-2 | 0.25 - 1 | Acute Tox.3 (H301) Repr.2 (H361d) | |

NonHazardous

| Chemical Name | EC No | CAS No | Weight-% | Classification according to Regulation (EC) No. 1272/2008 [CLP] | REACH Registration Number |
|---------------|-----------|-----------|----------|---|---------------------------|
| Gelatin | 232-554-6 | 9000-70-8 | * | Not Listed | |
| Mannitol | 200-711-8 | 69-65-8 | * | Not Listed | |

Full text of H- and EUH-phrases: see section 16

Additional information

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

| | |
|---------------------|--|
| Inhalation | Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately. |
| Eye contact | Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention. |
| Skin contact | Remove contaminated clothing and shoes. Wash skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention. |
| Ingestion | Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. |

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

Most important symptoms and effects See section 2 for classified hazards based on component information. See Section 11 for additional Toxicological Information

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

SAFETY DATA SHEET

Product Name Asenapine Sublingual Tablets (Greenstone LLC)
Revision date 05-Mar-2020

Page 3 / 8
Version 1.01

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Use carbon dioxide, dry chemical, or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

SAFETY DATA SHEET

Product Name Asenapine Sublingual Tablets (Greenstone LLC)
Revision date 05-Mar-2020

Page 4 / 8
Version 1.01

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

Asenapine maleate

Manufacturer OEL: 10 ug/m³

Gelatin

Russia

MAC: 10 mg/m³

Mannitol

Russia

MAC: 10 mg/m³

8.2. Exposure controls

Engineering controls Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental exposure controls No information available.

Personal protective equipment Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

SAFETY DATA SHEET

Product Name Asenapine Sublingual Tablets (Greenstone LLC)
Revision date 05-Mar-2020

Page 5 / 8
Version 1.01

| | |
|--------------------------------|--------------------|
| Physical state | Tablet |
| Color | White to off-white |
| Molecular formula (MF): | Mixture |
| Molecular weight | Mixture |
| Odor | No data available. |
| Odor threshold | No data available |

| <u>Property</u> | <u>Values</u> |
|---------------------------------------|-------------------|
| pH | No data available |
| Melting point / freezing point | No data available |
| Boiling point / boiling range | No data available |
| Flash point | No data available |
| Evaporation rate | No data available |
| Flammability (solid, gas) | No data available |
| Flammability Limit in Air | |
| Upper flammability limit: | No data available |
| Lower flammability limit: | No data available |
| Vapor pressure | No data available |
| Vapor density | No data available |
| Relative density | No data available |
| Water solubility | No data available |
| Solubility(ies) | No data available |
| Autoignition temperature | No data available |
| Decomposition temperature | No data available |
| Kinematic viscosity | No data available |
| Dynamic viscosity | No data available |
| Explosive properties | No data available |
| Oxidizing properties | No data available |

9.2. Other information

| | |
|-----------------------|-------------------|
| Liquid Density | No data available |
| Bulk density | No data available |

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

| | |
|-------------------|--------------------|
| Reactivity | No data available. |
|-------------------|--------------------|

10.2. Chemical stability

| | |
|------------------|--|
| Stability | Stable. under recommended storage and handling conditions. |
|------------------|--|

Explosion data

| | |
|---|--------------------|
| Sensitivity to Mechanical Impact | No data available. |
|---|--------------------|

| | |
|--|--------------------|
| Sensitivity to Static Discharge | No data available. |
|--|--------------------|

10.3. Possibility of hazardous reactions

| | |
|---|---------------------------|
| Possibility of hazardous reactions | No information available. |
|---|---------------------------|

| | |
|---------------------------------|-----------------|
| Hazardous polymerization | Will not occur. |
|---------------------------------|-----------------|

10.4. Conditions to avoid

| | |
|----------------------------|-------------|
| Conditions to avoid | None known. |
|----------------------------|-------------|

10.5. Incompatible materials

| | |
|-------------------------------|--|
| Incompatible materials | As a precautionary measure, keep away from strong oxidizers. |
|-------------------------------|--|

10.6. Hazardous decomposition products

| | |
|---|-------------|
| Hazardous decomposition products | None known. |
|---|-------------|

SAFETY DATA SHEET

Product Name Asenapine Sublingual Tablets (Greenstone LLC)
Revision date 05-Mar-2020

Page 6 / 8
Version 1.01

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

General Information: Toxicological properties of the formulation have not been investigated. The following information is available for the individual ingredients.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.

Known Clinical Effects: Effects reported during clinical use include a sudden, transient drop in blood pressure, dizziness, drowsiness, nausea, and sleepiness.

Acute Toxicity: (Species, Route, End Point, Dose)

Mannitol

Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Asenapine maleate

Rat Oral LD50 110-175

| Chemical Name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---------------|-----------------------|-------------|-----------------|
| Mannitol | = 13500 mg/kg (Rat) | - | - |

Irritation / Sensitization: (Study Type, Species, Severity)

Asenapine maleate

Antigenicity- Passive cutaneous anaphylaxis Guinea Pig No effect
Antigenicity- Active anaphylaxis Guinea Pig No effect
Antigenicity- Delayed skin reaction Guinea Pig No effect

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Asenapine maleate

Thirteen Week(s) Rat Oral 150 mg/kg/day Central nervous system
Thirteen Week(s) Rat Intravenous 5 mg/kg/day Central Nervous System
Thirteen Week(s) Dog Oral 160 mg/kg/day Central Nervous System
Fifty-two Week(s) Rat Oral 10.8 mg/kg/day Central Nervous System
Fifty-two Week(s) Dog Oral 3.6 mg/kg/day Central Nervous System

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Asenapine maleate

Peri-/Postnatal Development Rat Intravenous 1.0 mg/kg/day LOAEL Postnatal mortality
Prenatal & Postnatal Development Rat Intravenous 0.5 mg/kg/day NOAEL Not Teratogenic
Prenatal & Postnatal Development Rat Oral 30 mg/kg/day Maternal Toxicity, Embryotoxicity
Prenatal & Postnatal Development Rabbit Oral 15 mg/kg/day NOAEL Not Teratogenic, Neonatal toxicity
Prenatal & Postnatal Development Rabbit Intravenous 0.625 mg/kg/day NOAEL Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Asenapine maleate

Bacterial Mutagenicity (Ames) Negative
In Vivo Micronucleus Rat Negative
In Vitro Cytogenetics Human Lymphocytes Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Asenapine maleate

104 Week(s) Rat Subcutaneous 3.5 mg/kg/day mg/kg/day Not carcinogenic
104 Week(s) Mouse Subcutaneous 3.5 mg/kg/day Not carcinogenic

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

SAFETY DATA SHEET

Product Name Asenapine Sublingual Tablets (Greenstone LLC)
Revision date 05-Mar-2020

Page 7 / 8
Version 1.01

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Other adverse effects

Other adverse effects No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15: REGULATORY INFORMATION

SAFETY DATA SHEET

Product Name Asenapine Sublingual Tablets (Greenstone LLC)
Revision date 05-Mar-2020

Page 8 / 8
Version 1.01

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

Gelatin

| | |
|---|------------|
| CERCLA/SARA Section 313 de minimus % | Not Listed |
| California Proposition 65 | Not Listed |
| TSCA | Present |
| EINECS | 232-554-6 |
| AICS | Present |

Mannitol

| | |
|---|------------|
| CERCLA/SARA Section 313 de minimus % | Not Listed |
| California Proposition 65 | Not Listed |
| TSCA | Present |
| EINECS | 200-711-8 |
| AICS | Present |

Asenapine maleate

| | |
|---|------------|
| CERCLA/SARA Section 313 de minimus % | Not Listed |
| California Proposition 65 | Not Listed |
| EINECS | 288-064-8 |

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

Acute toxicity, oral-Cat.3;
H301 - Toxic if swallowed
Reproductive toxicity-Cat.2;
H361d - Suspected of damaging the unborn child

Prepared By Product Stewardship Hazard Communication
Global Environment, Health, and Safety Operations

Revision date 05-Mar-2020

Reason for revision Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.