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 Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company: MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain
Telephone: 44 1 670 59 30 00
Telefax: 908-735-1496
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Acute toxicity, Category 3
Acute toxicity, Category 4
Reproductive toxicity, Category 2
Specific target organ toxicity - single exposure, Category 1
Specific target organ toxicity - repeated exposure, Category 1
Short-term (acute) aquatic hazard, Category 1
Long-term (chronic) aquatic hazard, Category 1
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.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms: 

Image of 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.
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
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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenzo[2,3:6,7]oxepino[4,5-c]pyrrole maleate</td>
<td>85650-56-2</td>
<td>Acute Tox.3; H301 Acute Tox.3; H331 Rep.2; H361fd STOT SE1; H370 STOT RE1; H372 Aquatic Acute1; H400 Aquatic Chronic1; H410</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
</tbody>
</table>
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.

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 (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: 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 (NOx)

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 and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions: Discharge into the environment must be avoided. 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.
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. 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. 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, 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: Keep in properly labelled containers. Store locked up. Keep
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Asenapine Formulation

Version: 2.3
Revision Date: 23.03.2020
SDS Number: 691131-00011
Date of last issue: 13.09.2019
Date of first issue: 19.05.2016

areas and containers 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenzo[2,3;6,7]oxepino[4,5-c]pyrrole maleate</td>
<td>85650-56-2</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin
Wipe limit 10 µg/100 cm² 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.
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 NS 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.
- 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
- Relative density: No data available
- Density: No data available
- Solubility(ies): No data available
- Water solubility: Not applicable
- Partition coefficient: n-octanol/water: Not applicable
Asenapine Formulation

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
Ingestion
Eye contact

Acute toxicity
Toxic if swallowed.
Harmful if inhaled.
Asenapine Formulation

**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 malate:

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 malate:
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 malate:
Remarks: No data available

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.
Asenapine Formulation

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.
Asenapine Formulation

Components:

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

**Effects on fertility**
- Test Type: One-generation reproduction toxicity study
- 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

**Reproductive toxicity - Assessment**
- Test Type: Embryo-foetal development
- Species: Rabbit
- Application Route: Intravenous injection
- Developmental Toxicity: NOAEL: 0.626 mg/kg body weight
- Result: No teratogenic effects

**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 malate:**

**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.

Components:

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

**Exposure routes**
- Ingestion

**Target Organs**
- Central nervous system
Asenapine Formulation

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-dibenzo[2,3:6,7]oxepino[4,5-c]pyrrole malate:

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-dibenzo[2,3:6,7]oxepino[4,5-c]pyrrole malate:
Not applicable

Experience with human exposure

Components:

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

Ingestion: Symptoms: restlessness, Drowsiness, Dizziness, decrease in heart rate, hypotension
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

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

Not relevant

12.6 Other adverse effects

No data available

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

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>ADN</strong></td>
<td>UN 2811</td>
</tr>
<tr>
<td><strong>ADR</strong></td>
<td>UN 2811</td>
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<tr>
<td><strong>RID</strong></td>
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<tr>
<td><strong>IMDG</strong></td>
<td>UN 2811</td>
</tr>
<tr>
<td><strong>IATA</strong></td>
<td>UN 2811</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ADN</strong></td>
<td>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)</td>
</tr>
<tr>
<td><strong>ADR</strong></td>
<td>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)</td>
</tr>
<tr>
<td><strong>RID</strong></td>
<td>TOXIC SOLID, ORGANIC, N.O.S.</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Asenapine Formulation

Version 2.3  Revision Date: 23.03.2020  SDS Number: 691131-00011  Date of last issue: 13.09.2019
Date of first issue: 19.05.2016

IMDG: TOXIC SOLID, ORGANIC, N.O.S.
IATA: Toxic solid, organic, n.o.s.

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       | lh=III, lh=60, lh=6.1 |
| Classification Code: T2 |
| Hazard Identification Number: 60 |
| Labels: 6.1 |

| ADR       | lh=III, lh=60, lh=6.1 |
| Classification Code: T2 |
| Hazard Identification Number: 60 |
| Labels: 6.1 |
| Tunnel restriction code: (E) |

| RID       | lh=III, lh=60, lh=6.1 |
| Classification Code: T2 |
| Hazard Identification Number: 60 |
| Labels: 6.1 |

| IMDG      | lh=III, lh=6.1, EmS: F-A, S-A |
| Labels: 6.1 |

| IATA (Cargo) | lh=677, lh=Y645 |
| Packing group: III |
| Labels: Toxic |

| IATA (Passenger) | lh=670, lh=Y645 |
| Packing group: III |

(trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate)
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Asenapine Formulation

Labels

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 pollutants (recast) : Not applicable

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


<table>
<thead>
<tr>
<th>H3</th>
<th>STOT SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quantity 1 50 t</td>
</tr>
<tr>
<td></td>
<td>Quantity 2 200 t</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100 t 200 t</td>
</tr>
</tbody>
</table>

Other regulations:

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

Young people under the age of 18 are not allowed to use or be exposed to the product profes-
Asenapine Formulation

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

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; AICS - Australian Inventory of Chemical Substances; 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 Organisa-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006
Asenapine Formulation

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Further information

Classification of the mixture:
Acute Tox. 3 H301 Calculation method
Acute Tox. 4 H332 Calculation method
Repr. 2 H361fd Calculation method
STOT SE 1 H370 Calculation method
STOT RE 1 H372 Calculation method
Aquatic Acute 1 H400 Calculation method
Aquatic Chronic 1 H410 Calculation method

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