1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Suvorexant Formulation

Supplier’s company name, address and phone number

Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.
Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Short-term (acute) aquatic hazard : Category 2
Long-term (chronic) aquatic hazard : Category 3

GHS label elements
Hazard pictograms : None
Signal word : None
Hazard statements : H401 Toxic to aquatic life.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : Prevention:
P273 Avoid release to the environment.

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

Other hazards which do not result in classification
Important symptoms and outlines of the emergency assumed : 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.
SAFETY DATA SHEET

Suvorexant Formulation

Version 6.0  Revision Date: 2021/08/27  SDS Number: 21542-00019  Date of last issue: 2021/04/09  Date of first issue: 2014/10/14

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Suvorexant</td>
<td>1030377-33-3</td>
<td>&gt;= 2.5 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-611</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Silicon, amorphous</td>
<td>112945-52-5</td>
<td>&gt;= 0.1 - 1</td>
<td>1-548</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

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

If inhaled: If inhaled, remove to fresh air. Get medical attention if symptoms occur.

In case of skin contact: Wash with water and soap. Get medical attention if symptoms occur.

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. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray  Alcohol-resistant foam  Carbon dioxide (CO2)  Dry chemical

Unsuitable extinguishing media: None known.

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  Metal oxides

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions:
Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Handling
Technical measures:
Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

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

Storage
Conditions for safe storage: Keep in properly labelled containers. Store in accordance with the particular national regulations.
Materials to avoid: Do not store with the following product types: Strong oxidizing agents
Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Reference concentration / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suvorexant</td>
<td>1030377-33-3</td>
<td>TWA</td>
<td>20 µg/m3 (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>200 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type: Particulates type
Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

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

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

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : Not applicable

Decomposition temperature : No data available

pH : No data available

Evaporation rate : Not applicable

Auto-ignition temperature : No data available
Viscosity
  Viscosity, kinematic : Not applicable

Solubility(ies)
  Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : Not applicable

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

Relative vapour density : Not applicable

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics
  Particle size : No data available

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.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.
Components:

Suvorexant:

Acute oral toxicity: LD50 (Rat): > 1,200 mg/kg
LD50 (Dog): > 1,125 mg/kg
LDLo (Mouse): 2,000 mg/kg

Magnesium stearate:

Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Remarks: Based on data from similar materials

Silicon, amorphous:

Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials

Acute inhalation toxicity: LC50 (Rat): > 2.08 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg
Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:

Suvorexant:

Species: Rabbit
Result: No skin irritation

Magnesium stearate:

Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

Silicon, amorphous:

Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Suvorexant:
- Species: Bovine cornea
- Result: Mild eye irritation
- Method: Bovine cornea (BCOP)

Magnesium stearate:
- Species: Rabbit
- Result: No eye irritation
- Remarks: Based on data from similar materials

Silicon, amorphous:
- Species: Rabbit
- Result: No eye irritation
- Method: OECD Test Guideline 405
- Remarks: Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Suvorexant:
- Test Type: Local lymph node assay (LLNA)
- Species: Mouse
- Assessment: Does not cause skin sensitisation.
- Result: negative

Magnesium stearate:
- Test Type: Maximisation Test
- Exposure routes: Skin contact
- Species: Guinea pig
- Method: OECD Test Guideline 406
- Result: negative
- Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.
## Components:

### Suvorexant:

**Genotoxicity in vitro**
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- Test Type: Alkaline elution assay
  - Test system: rat hepatocytes
  - Result: negative
- Test Type: Chromosomal aberration
  - Test system: Chinese hamster ovary cells
  - Result: negative

**Genotoxicity in vivo**
- Test Type: Micronucleus test
  - Species: Mouse
  - Result: negative
- Test Type: Micronucleus test
  - Species: Rat
  - Result: negative

### Magnesium stearate:

**Genotoxicity in vitro**
- Test Type: In vitro mammalian cell gene mutation test
  - Result: negative
  - Remarks: Based on data from similar materials
- Test Type: Chromosome aberration test in vitro
  - Method: OECD Test Guideline 473
  - Result: negative
  - Remarks: Based on data from similar materials
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Remarks: Based on data from similar materials

### Silicon, amorphous:

**Genotoxicity in vitro**
- Test Type: Bacterial reverse mutation assay (AMES)
  - Method: OECD Test Guideline 471
  - Result: negative
  - Remarks: Based on data from similar materials

**Genotoxicity in vivo**
- Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative
  - Remarks: Based on data from similar materials

### Carcinogenicity

Not classified based on available information.
Components:

Suvorexant:

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 month(s)</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Silicon, amorphous:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>103 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Reproductive toxicity

Not classified based on available information.

Components:

Suvorexant:

Effects on fertility:

| Test Type: Fertility/early embryonic development |
| Species: Rat, male and female                  |
| Application Route: Oral                        |
| General Toxicity: Parent: NOAEL: >= 325 mg/kg body weight |
| Result: negative                              |

Effects on foetal development:

| Test Type: Embryo-foetal development |
| Species: Rabbit, female               |
| Application Route: Oral               |
| Developmental Toxicity: NOAEL: 150 mg/kg body weight |
| Result: negative                      |

| Test Type: Embryo-foetal development |
| Species: Rat                         |
| Application Route: Oral              |
| Developmental Toxicity: NOAEL: 80 mg/kg body weight |
| Result: negative                     |

Magnesium stearate:

Effects on fertility:

| Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test |
| Species: Rat                                                                                       |
| Application Route: Ingestion                                                                     |
| Method: OECD Test Guideline 422                                                                    |
| Result: negative                                                                                 |
| Remarks: Based on data from similar materials                                                   |
### Effects on foetal development

<table>
<thead>
<tr>
<th>Species</th>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>Species: Rat</td>
</tr>
<tr>
<td>Result</td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td>Remarks</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

Silicon, amorphous:

<table>
<thead>
<tr>
<th>Species</th>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>Species: Rat</td>
</tr>
<tr>
<td>Result</td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td>Remarks</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

### STOT - single exposure

Not classified based on available information.

**Components:**

**Suvorexant:**

| Remarks       | Based on human experience. |

### STOT - repeated exposure

Not classified based on available information.

**Components:**

**Suvorexant:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Exposure routes: Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Target Organs: Central nervous system</td>
</tr>
<tr>
<td>Application Route</td>
<td>LOAEL: 1,200 mg/kg</td>
</tr>
<tr>
<td>Exposure time</td>
<td>Target Organs: Blood, Pancreas</td>
</tr>
</tbody>
</table>

Repeated dose toxicity

**Components:**

**Suvorexant:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Species: Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>NOAEL: 50 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>Target Organs: Blood, Liver, Central nervous system</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Species: Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>NOAEL: 75 mg/kg</td>
</tr>
</tbody>
</table>
Suvorexant Formulation

11. TOXICOLOGICAL INFORMATION

LOAEL: 300 mg/kg
Application Route: Oral
Exposure time: 180 d
Target Organs: Pancreas, Blood, Stomach

Species: Dog
NOAEL: 50 mg/kg
LOAEL: 125 mg/kg
Application Route: Oral
Exposure time: 270 d
Target Organs: Blood

Species: Rat
NOAEL: 40 mg/kg
LOAEL: 80 mg/kg
Application Route: Oral
Exposure time: 18 Months
Target Organs: Eye, Central nervous system

Magnesium stearate:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

Silicon, amorphous:
Species: Rat
NOAEL: 1.3 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 13 Weeks
Remarks: Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Suvorexant:
Ingestion: Symptoms: Drowsiness, Headache, abnormal dreams, Fatigue, Dizziness, dry mouth, Nausea, liver function change, upper respiratory tract infection, urinary tract infection, Cough, Diarrhoea, Palpitation, tachycardia

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Suvorexant:
Toxicity to daphnia and other aquatic invertebrates

- **EC50** (Mysidopsis bahia (opossum shrimp)): 0.56 mg/l
  - Exposure time: 96 h

Toxicity to algae/aquatic plants

- **EC50** (Pseudokirchneriella subcapitata (green algae)): > 5 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

  NOEC (Pseudokirchneriella subcapitata (green algae)): 2.5 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

**M-Factor (Acute aquatic toxicity)**: 1

Toxicity to fish (Chronic toxicity)

- **NOEC** (Pimephales promelas (fathead minnow)): 0.14 mg/l
  - Exposure time: 32 d
  - Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

- **NOEC** (Daphnia magna (Water flea)): 0.5 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

Toxicity to microorganisms

- **EC50**: > 1,000 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

  NOEC: 1,000 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

**Magnesium stearate:**

Toxicity to fish

- **LC50** (Leuciscus idus (Golden orfe)): > 100 mg/l
  - Exposure time: 48 h
  - Method: DIN 38412
  - Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates

- **EL50** (Daphnia magna (Water flea)): > 1 mg/l
  - Exposure time: 47 h
  - Test substance: Water Accommodated Fraction
  - Remarks: Based on data from similar materials
  - No toxicity at the limit of solubility

Toxicity to algae/aquatic plants

- **EL50** (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
  - Exposure time: 72 h
  - Test substance: Water Accommodated Fraction
  - Method: OECD Test Guideline 201
  - Remarks: Based on data from similar materials
  - No toxicity at the limit of solubility
### NOELR (Pseudokirchneriella subcapitata (green algae))
- Exposure time: 72 h
- Test substance: Water Accommodated Fraction
- Method: OECD Test Guideline 201
- Remarks: Based on data from similar materials

### EC10 (Pseudomonas putida)
- Exposure time: 16 h
- Test substance: Water Accommodated Fraction
- Remarks: Based on data from similar materials

### Silicon, amorphous:

#### Toxicity to fish
- LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
- Exposure time: 96 h
- Method: OECD Test Guideline 203
- Remarks: Based on data from similar materials

#### Toxicity to daphnia and other aquatic invertebrates
- EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
- Exposure time: 24 h
- Method: OECD Test Guideline 202
- Remarks: Based on data from similar materials

#### Toxicity to algae/aquatic plants
- EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201
- Remarks: Based on data from similar materials

#### NOEC (Desmodesmus subspicatus (green algae))
- Exposure time: 72 h
- Method: OECD Test Guideline 201
- Remarks: Based on data from similar materials

### Persistence and degradability

#### Components:

**Suvorexant:**
- **Biodegradability**: Result: Not readily biodegradable.
  - Biodegradation: 81 %
  - Exposure time: 28 d
  - Method: OECD Test Guideline 314

**Magnesium stearate:**
- **Biodegradability**: Result: Not biodegradable
- Remarks: Based on data from similar materials

---

**Silicon, amorphous:**
- **Toxicity to microorganisms**: NOELR
- **Exposure time**: 72 h
- **Test substance**: Water Accommodated Fraction
- **Method**: OECD Test Guideline 201
- **Remarks**: Based on data from similar materials

**Silicon, amorphous:**
- **Toxicity to fish**: LC50
- **Exposure time**: 96 h
- **Test substance**: Water Accommodated Fraction
- **Method**: OECD Test Guideline 203
- **Remarks**: Based on data from similar materials

**Silicon, amorphous:**
- **Toxicity to daphnia and other aquatic invertebrates**: EC50
- **Exposure time**: 24 h
- **Test substance**: Water Accommodated Fraction
- **Method**: OECD Test Guideline 202
- **Remarks**: Based on data from similar materials

**Silicon, amorphous:**
- **Toxicity to algae/aquatic plants**: EC50
- **Exposure time**: 72 h
- **Test substance**: Water Accommodated Fraction
- **Method**: OECD Test Guideline 201
- **Remarks**: Based on data from similar materials

**Silicon, amorphous:**
- **NOEC**:
- **Exposure time**: 72 h
- **Test substance**: Water Accommodated Fraction
- **Method**: OECD Test Guideline 201
- **Remarks**: Based on data from similar materials
Bioaccumulative potential

Components:

Suvorexant:

Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 358
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water: log Pow: 4.04

Magnesium stearate:

Partition coefficient: n-octanol/water: log Pow: > 4

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: Not applicable
Proper shipping name: Not applicable
Class: Not applicable
Subsidiary risk: Not applicable
Packing group: Not applicable
Labels: Not applicable

IATA-DGR
UN/ID No.: Not applicable
Proper shipping name: Not applicable
Class: Not applicable
Subsidiary risk: Not applicable
Packing group: Not applicable
Labels: Not applicable
Packing instruction (cargo aircraft): Not applicable
Packing instruction (passenger aircraft): Not applicable
SAFETY DATA SHEET

Suvorexant Formulation

IMDG-Code
- UN number: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable
- EmS Code: Not applicable
- Marine pollutant: Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
Refer to section 15 for specific national regulation.

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

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

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
</tr>
<tr>
<td>Crystalline silica</td>
<td>165 2</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)
SAFETY DATA SHEET

Suvorexant Formulation

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
</tr>
<tr>
<td>Crystalline silica</td>
<td>165</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
16. OTHER INFORMATION

Further information

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

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average

AICL - 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; ICS0 - 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 Standardisation; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - 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

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 mate-
rial 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 ap-
propriateness of the SDS material in the user’s end product, if applicable.

JP / EN