SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Suvorexant Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 26 Talavera Road, Talavera Corp Centre, Macquarie Park
New South Wales, 2113 Australia
Telephone: (61)-02-8988-8000
Emergency telephone number: (61)-02-8988-8000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards which do not result in classification
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
<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suvorexant</td>
<td>1030377-33-3</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&lt; 10</td>
</tr>
</tbody>
</table>

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.
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.

SECTION 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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

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.

Methods and materials for: Sweep up or vacuum up spillage and collect in suitable con-
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:
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.

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.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of)</th>
<th>Control parameters / Permissible</th>
<th>Basis</th>
</tr>
</thead>
</table>

3 / 15
### 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

- Chemical-resistant gloves

#### Eye protection

- Wear safety glasses with side shields or 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., sleevelents, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
- Use appropriate degowning techniques to remove potentially contaminated clothing.

#### Further information

This value is for inhalable dust containing no asbestos and < 1% crystalline silica.

### Section 9. Physical and Chemical Properties

- **Appearance**: Powder
- **Colour**: No data available
- **Odour**: No data available
Odour Threshold : No data available
pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : Not applicable
Evaporation rate : Not applicable
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : Not applicable
Relative vapour density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available
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

**Exposure routes:**
- Inhalation
- Skin contact
- Ingestion
- Eye contact

**Acute toxicity:**
Not classified based on available information.

**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

**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
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

**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

**Chronic toxicity**

**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

Carcinogenicity
Not classified based on available information.

Components:
Suvorexant:
Species: Mouse
Application Route: Oral
Exposure time: 6 month(s)
Result: negative

Species: Rat
Application Route: Oral
Exposure time: 2 Years
Result: negative

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
SAFETY DATA SHEET
Suvorexant Formulation

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:
- Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative
  - Remarks: Based on data from similar materials

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:
Exposure routes: Ingestion
Target Organs: Central nervous system
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Suvorexant:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
<th>325 mg/kg</th>
<th>1,200 mg/kg</th>
<th>Oral</th>
<th>30 d</th>
<th>Blood, Pancreas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Dog</td>
<td>50 mg/kg</td>
<td>125 mg/kg</td>
<td>Oral</td>
<td>30 d</td>
<td>Blood, Liver, Central nervous system</td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
<td>75 mg/kg</td>
<td>300 mg/kg</td>
<td>Oral</td>
<td>180 d</td>
<td>Pancreas, Blood, Stomach</td>
</tr>
<tr>
<td>Species</td>
<td>Dog</td>
<td>50 mg/kg</td>
<td>125 mg/kg</td>
<td>Oral</td>
<td>270 d</td>
<td>Blood</td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
<td>40 mg/kg</td>
<td>80 mg/kg</td>
<td>Oral</td>
<td>18 Months</td>
<td>Eye, Central nervous system</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

| Species | Rat | > 100 mg/kg | Ingestion | 90 Days | 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
SECTION 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
Method: US-EPA OPPTS 850.1035

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

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)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms: EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
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

Stability in water: Hydrolysis: < 10 % (5 d)
Method: OECD Test Guideline 111

Magnesium stearate:
Biodegradability: Result: Not biodegradable
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
SECTION 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations
UNRTDG
Not regulated as a dangerous good
IATA-DGR
Not regulated as a dangerous good
IMDG-Code
Not regulated as a dangerous good

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

National Regulations
ADG
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

Prohibition/Licensing Requirements: There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined
### SAFETY DATA SHEET

**Suvorexant Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

### SECTION 16. OTHER INFORMATION

<table>
<thead>
<tr>
<th>Further information</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision Date</td>
<td>09/13/2019</td>
<td></td>
</tr>
<tr>
<td>Date format</td>
<td>dd.mm.yyyy</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Full text of other abbreviations</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
<td></td>
</tr>
<tr>
<td>AU OEL</td>
<td>Australia. Workplace Exposure Standards for Airborne Contaminants.</td>
<td></td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
<td></td>
</tr>
<tr>
<td>AU OEL / TWA</td>
<td>Exposure standard - time weighted average</td>
<td></td>
</tr>
</tbody>
</table>

| AICS - Australian Inventory of Chemical Substances; 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 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; 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-
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.

AU / EN