SAFETY DATA SHEET

Suvorexant Formulation

Version 3.13 Revision Date: 16.10.2020 SDS Number: 21519-00017 Date of last issue: 23.03.2020

Date of first issue: 14.10.2014

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 (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: Sweep up or vacuum up spillage and collect in suitable con-
containment and cleaning up

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.

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>

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**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
- **Material**: Chemical-resistant gloves
- **Remarks**: Consider double gloving.

**Eye protection**

- **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**

- **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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- **Appearance**: Powder
- **Colour**: No data available
- **Odour**: No data available
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>
SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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
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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
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Application Route: Oral
General Toxicity - Parent: NOAEL: \( \geq 325 \text{ mg/kg body weight} \)
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**

| 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:
Species: Rat
NOAEL: 325 mg/kg
LOAEL: 1,200 mg/kg
Application Route: Oral
Exposure time: 30 d
Target Organs: Blood, Pancreas

Species: Dog
NOAEL: 50 mg/kg
LOAEL: 125 mg/kg
Application Route: Oral
Exposure time: 30 d
Target Organs: Blood, Liver, Central nervous system

Species: Rat
NOAEL: 75 mg/kg
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

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:**
- Toxicty 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
- Toxicty 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
- Toxicty to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.14 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
- Toxicty 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
- Toxicty 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:**
- Toxicty to fish: LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l Exposure time: 48 h Method: DIN 38412 Remarks: Based on data from similar materials
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

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

EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l

Toxicity to microorganisms:
- Test substance: Water Accommodated Fraction
- Exposure time: 16 h
- Remarks: Based on data from similar materials

EC10 (Pseudomonas putida): > 100 mg/l

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
octanol/water

**Mobility in soil**
No data available

**Other adverse effects**
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, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

**The components of this product are reported in the following inventories:**

- **AICS**: not determined
- **DSL**: not determined
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</table>

**IECSC** : not determined

### SECTION 16. OTHER INFORMATION

**Further information**

- **Revision Date** : 16.10.2020
- **Date format** : dd.mm.yyyy

**Full text of other abbreviations**

- ACGIH : USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA : 8-hour, time-weighted average
- AU OEL / TWA : Exposure standard - time weighted average

- All abbreviations are defined in the text.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be...
considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

AU / EN