

# SAFETY DATA SHEET



## Suvorexant Formulation

Version 12.1      Revision Date: 2025/04/14      SDS Number: 21542-00027      Date of last issue: 2024/09/28  
Date of first issue: 2014/10/14

---

### 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

Restrictions on use : Not applicable

---

### 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 as- : Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of

# SAFETY DATA SHEET



## Suvorexant Formulation

Version 12.1	Revision Date: 2025/04/14	SDS Number: 21542-00027	Date of last issue: 2024/09/28 Date of first issue: 2014/10/14
-----------------	------------------------------	----------------------------	---

sumed the skin.  
May form explosive dust-air mixture during processing, handling or other means.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Suvorexant	1030377-33-3	>= 2.5 - < 10	
Magnesium stearate	557-04-0	>= 1 - < 10	2-611

### 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 (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire-fighting : 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.

**Suvorexant Formulation**Version  
12.1Revision Date:  
2025/04/14SDS Number:  
21542-00027Date of last issue: 2024/09/28  
Date of first issue: 2014/10/14

---

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.

# SAFETY DATA SHEET



## Suvorexant Formulation

Version  
12.1

Revision Date:  
2025/04/14

SDS Number:  
21542-00027

Date of last issue: 2024/09/28  
Date of first issue: 2014/10/14

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.

: Oxidizing agents

: 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.

Avoidance of contact  
Hygiene measures

### 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

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Concentra- tion standard / Permissible con- centration	Basis
Suvorexant	1030377-33-3	TWA	14 µg/m3 (OEB 3)	Internal
		Wipe limit	140 µg/100 cm <sup>2</sup>	Internal
Magnesium stearate	557-04-0	TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
		TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH

**Suvorexant Formulation**

---

Version 12.1	Revision Date: 2025/04/14	SDS Number: 21542-00027	Date of last issue: 2024/09/28 Date of first issue: 2014/10/14
-----------------	------------------------------	----------------------------	---

---

<b>Engineering measures</b>	: 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.
<b>Personal protective equipment</b>	
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

# SAFETY DATA SHEET



## Suvorexant Formulation

Version 12.1      Revision Date: 2025/04/14      SDS Number: 21542-00027      Date of last issue: 2024/09/28  
Date of first issue: 2014/10/14

---

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available  
per flammability limit

Lower explosion limit / : No data available  
Lower flammability limit

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 reac- : May form explosive dust-air mixture during processing, han-  
tions : dling or other means.

# SAFETY DATA SHEET



## Suvorexant Formulation

Version  
12.1

Revision Date:  
2025/04/14

SDS Number:  
21542-00027

Date of last issue: 2024/09/28  
Date of first issue: 2014/10/14

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.

## 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : 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

# SAFETY DATA SHEET



## Suvorexant Formulation

Version  
12.1

Revision Date:  
2025/04/14

SDS Number:  
21542-00027

Date of last issue: 2024/09/28  
Date of first issue: 2014/10/14

---

### 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

### 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

# SAFETY DATA SHEET



## Suvorexant Formulation

Version  
12.1

Revision Date:  
2025/04/14

SDS Number:  
21542-00027

Date of last issue: 2024/09/28  
Date of first issue: 2014/10/14

---

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:**

# SAFETY DATA SHEET



## Suvorexant Formulation

Version  
12.1

Revision Date:  
2025/04/14

SDS Number:  
21542-00027

Date of last issue: 2024/09/28  
Date of first issue: 2014/10/14

---

### Effects on fertility

: Test Type: Fertility/early embryonic development  
Species: Rat, male and female  
Application Route: Oral  
General Toxicity - Parent: NOAEL:  $\geq$  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

: 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.

# SAFETY DATA SHEET



## Suvorexant Formulation

Version  
12.1

Revision Date:  
2025/04/14

SDS Number:  
21542-00027

Date of last issue: 2024/09/28  
Date of first issue: 2014/10/14

### 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.

**Suvorexant Formulation**Version  
12.1Revision Date:  
2025/04/14SDS Number:  
21542-00027Date of last issue: 2024/09/28  
Date of first issue: 2014/10/14**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  
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

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

**Suvorexant Formulation**Version  
12.1Revision Date:  
2025/04/14SDS Number:  
21542-00027Date of last issue: 2024/09/28  
Date of first issue: 2014/10/14**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 materialsToxicity to daphnia and other  
aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 1 mg/l  
Exposure time: 47 h  
Test substance: Water Accommodated Fraction  
Method: Directive 67/548/EEC, Annex V, C.2.  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubilityToxicity 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 solubilityNOELR (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

# SAFETY DATA SHEET



## Suvorexant Formulation

Version  
12.1

Revision Date:  
2025/04/14

SDS Number:  
21542-00027

Date of last issue: 2024/09/28  
Date of first issue: 2014/10/14

---

### 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.  
Do not dispose of waste into sewer.

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  
Environmentally hazardous : no

##### **IATA-DGR**

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable

# SAFETY DATA SHEET



## Suvorexant Formulation

Version 12.1      Revision Date: 2025/04/14      SDS Number: 21542-00027      Date of last issue: 2024/09/28  
Date of first issue: 2014/10/14

---

Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

### 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

# SAFETY DATA SHEET



## Suvorexant Formulation

Version 12.1 Revision Date: 2025/04/14 SDS Number: 21542-00027 Date of last issue: 2024/09/28 Date of first issue: 2014/10/14

### Substances Subject to be Notified Names

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

Chemical name	Concentration (%)	Remarks
Magnesium stearate	>=1 - <10	-

### Substances Subject to be Indicated Names

Law Article 57 (Ministerial Order Article 30 Appended Table 2)

Chemical name	Remarks
Magnesium stearate	-

### Skin and Eye Damage Substances (ISHL MO Art. 594-2)

Not applicable

### Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

### 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

# SAFETY DATA SHEET



## Suvorexant Formulation

Version 12.1 Revision Date: 2025/04/14 SDS Number: 21542-00027 Date of last issue: 2024/09/28 Date of first issue: 2014/10/14

---

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

IECSC : not determined

---

## 16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : yyyy/mm/dd

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AIIC - 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; 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

# SAFETY DATA SHEET



## Suvorexant Formulation

Version  
12.1

Revision Date:  
2025/04/14

SDS Number:  
21542-00027

Date of last issue: 2024/09/28  
Date of first issue: 2014/10/14

---

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 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.

JP / EN