

# **Suvorexant Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 12.0 2024/09/28 21542-00026 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 out: : lines of the emergency as-

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of





SDS Number: Date of last issue: 2024/04/06 Version Revision Date: 12.0 2024/09/28 21542-00026 Date of first issue: 2014/10/14

sumed the skin.

May form explosive dust-air mixture during processing, han-

dling 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 ad-

vice 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.

If in eyes, rinse well with water. In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting. If swallowed

Get medical attention if symptoms occur.

Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

Protection of first-aiders

delayed

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. 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).

Treat symptomatically and supportively. Notes to physician

#### 5. FIREFIGHTING MEASURES

Suitable extinguishing media Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

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.





Version Revision Date: SDS Number: Date of last issue: 2024/04/06 12.0 2024/09/28 21542-00026 Date of first issue: 2014/10/14

Hazardous combustion prod- :

ucts

Carbon oxides

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 con-

tainer 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 deter-

mine 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.



# **Suvorexant Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 12.0 2024/09/28 21542-00026 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 as-

sessment

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

Hygiene measures

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.

**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 parameters / Concentration standard / Permissible concentration	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 (Respirable particulate matter)	3 mg/m3	ACGIH



# **Suvorexant Formulation**

SDS Number: Date of last issue: 2024/04/06 Version Revision Date: 12.0 2024/09/28 21542-00026 Date of first issue: 2014/10/14

**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 con-

tainment devices). Minimize open handling.

Personal protective equipment

Respiratory protection If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection Particulates type

Material Chemical-resistant gloves

Consider double gloving. Remarks

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.

Work uniform or laboratory coat. Skin and body protection

> Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-

posable 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, han-

dling or other means.

Flammability (liquids) No data available



# **Suvorexant Formulation**

SDS Number: Date of last issue: 2024/04/06 Version **Revision Date:** 12.0 2024/09/28 21542-00026 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 / Lower flammability limit No data available

Flash point Not applicable

No data available Decomposition temperature

pΗ 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

No data available Relative density

No data available Density

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-

dling or other means. tions

6/18

May form explosive dust-air mixture during processing, han-



# **Suvorexant Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 12.0 2024/09/28 21542-00026 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

Hazardous decomposition

products

Oxidizing agents

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 tox-

icity

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



# **Suvorexant Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 12.0 2024/09/28 21542-00026 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



# **Suvorexant Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 12.0 2024/09/28 21542-00026 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:



# **Suvorexant Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 12.0 2024/09/28 21542-00026 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: >= 325 mg/kg body weight

Result: negative

Effects on foetal develop-

ment

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 develop-

ment

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.



# **Suvorexant Formulation**

SDS Number: Date of last issue: 2024/04/06 Version Revision Date: 12.0 2024/09/28 21542-00026 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 Exposure time : Oral

: 30 d : Blood, Pancreas Target Organs

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

: Pancreas, Blood, Stomach Target Organs

Species Dog NOAEL 50 mg/kg 125 mg/kg LOAEL 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 Revision Date: SDS Number: Date of last issue: 2024/04/06 12.0 2024/09/28 21542-00026 Date of first issue: 2014/10/14

## **Experience with human exposure**

## **Components:**

#### Suvorexant:

Ingestion : Symptoms: Drowsiness, Headache, abnormal dreams, Fa-

tigue, 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 tox-

icity)

. .

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic 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 Revision Date: SDS Number: Date of last issue: 2024/04/06 12.0 2024/09/28 21542-00026 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 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 Method: Directive 67/548/EEC, Annex V, C.2. 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

ma/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



# **Suvorexant Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 12.0 2024/09/28 21542-00026 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-

: log Pow: > 4

octanol/water

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 han-

dling 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

no

Environmentally hazardous :

IATA-DGR

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



# **Suvorexant Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 12.0 2024/09/28 21542-00026 Date of first issue: 2014/10/14

Labels : Not applicable Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen- : Not

ger aircraft)

Not applicable

**IMDG-Code** 

**UN** number Not applicable Not applicable Proper shipping name Not applicable Class Not applicable Subsidiary risk 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



# **Suvorexant Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 12.0 2024/09/28 21542-00026 Date of first issue: 2014/10/14

# **Substances Subject to be Notified Names**

Article 57-2 (Enforcement Order Table 9)

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

# Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
Magnesium stearate	-

## Skin and Eye Damage Substances for PPE Requirements (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



# **Suvorexant Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 12.0 2024/09/28 21542-00026 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 Agen-

cy, http://echa.europa.eu/

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

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 Con-



# **Suvorexant Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 12.0 2024/09/28 21542-00026 Date of first issue: 2014/10/14

centration 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 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