according to the Globally Harmonized System



## **Suvorexant Formulation**

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#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Suvorexant Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number: +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

## 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

#### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

**GHS Classification** 

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.

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#### 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.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Suvorexant	1030377-33-3	>= 5 - < 10
Magnesium stearate	557-04-0	>= 1 - < 5

### 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 If swallowed, DO NOT induce vomiting.

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

Most important symptoms

and effects, both acute and

delayed

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. Protection of first-aiders First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

media

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.

Hazardous combustion prod: :

ucts

Carbon oxides Metal oxides

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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

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 Advice on safe handling Use only with adequate ventilation.

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 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.

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Take care to prevent spills, waste and minimize release to the

environment.

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

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / 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

**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 contain-

ment 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 : 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

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suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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.

#### 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, han-

dling 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)

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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

### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

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

dling or other means.

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

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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

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Suvorexant:

Species : Bovine cornea

Method : Bovine cornea (BCOP)
Result : Mild eye irritation

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

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Assessment : Does not cause skin sensitisation.

Result : negative

Magnesium stearate:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

Suvorexant:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Alkaline elution assay Test system: rat hepatocytes

Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Result: negative

Test Type: Micronucleus test

Species: Rat Result: negative

Magnesium stearate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

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### **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

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

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### 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

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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, Fa-

tique, Dizziness, dry mouth, Nausea, liver function change, upper respiratory tract infection, urinary tract infection, Cough,

Diarrhoea, Palpitation, tachycardia

12. ECOLOGICAL INFORMATION

**Ecotoxicity** 

**Components:** 

**Suvorexant:** 

aquatic invertebrates

Toxicity to daphnia and other : 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

ma/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- : 1

icity)

Toxicity to microorganisms EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

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NOEC: 1,000 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.14 mg/l Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.5 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

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

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:**

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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

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

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** 

Not regulated as a dangerous good

**IATA-DGR** 

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#### **IMDG-Code**

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

#### 15. REGULATORY INFORMATION

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

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

**AICS** not determined

DSL not determined

**IECSC** not determined

## 16. OTHER INFORMATION

**Revision Date** 26.09.2023

**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/

Date format dd.mm.yyyy

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

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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.

IN / EN