

## Suvorexant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
2.3	28.09.2024	21538-00026	Date of first issue: 14.10.2014

### **SECTION 1:** Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier Trade name	:	Suvorexant Formulation
1.2	Relevant identified uses of th	e s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture		Pharmaceutical
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	saf	ety data sheet
	Company	:	MSD Piercetown A86 HD21 Dunboyne, Ireland
	Telephone	:	908-740-4000
	E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

## **SECTION 2: Hazards identification**

### 2.1 Classification of the substance or mixture

<b>Classification (REGULATIO</b> Long-term (chronic) aquatic egory 3		. ,	<b>72/2008)</b> H412: Harmful to aquatic life with long lasting ef- fects.
2.2 Label elements			
Labelling (REGULATION (E	EC)	No 1272/20	08)
Hazard statements	:	H412	Harmful to aquatic life with long lasting effects.
Precautionary statements	:	<b>Preventio</b> P273	<b>n:</b> Avoid release to the environment.



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#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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**

#### 3.2 Mixtures

#### Components

Componentia			-
Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Suvorexant	1030377-33-3	STOT SE 3; H336 STOT RE 2; H373 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 2; H411 M-Factor (Acute aquatic toxicity): 1	>= 2.5 - < 10

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

#### 4.1 Description of 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.
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).

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

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lf i	If inhaled		-	If inhaled, remove to fresh air. Get medical attention if symptoms occur.	
In	case of skin contact	:	Wash with water Get medical atter	and soap. tion if symptoms occur.	
In	case of eye contact	:	- ,	ell with water. tion if irritation develops and persists.	
lf s	swallowed	:	Get medical atten	NOT induce vomiting. tion if symptoms occur. bughly with water.	
4.2 Mo	st important symptoms a	nd e	effects, both acute	and delayed	
	sks	:	Contact with dust the skin.	can cause mechanical irritation or drying of the eyes can lead to mechanical irritation.	
4.3 Ind	ication of any immediate	med	dical attention and	I special treatment needed	
Tr	eatment	:	Treat symptomati	cally and supportively.	
	inguishing media iitable extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical		
	nsuitable extinguishing edia	:	None known.		
5.2 Sp	ecial hazards arising from	n the	e substance or mi	xture	
Sp	becific hazards during fire- hting	:	Avoid generating concentrations, a potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a	
Ha uc	azardous combustion prod- ts	:	Carbon oxides Metal oxides		
5.3 Ad	vice for firefighters				
Sp	pecial protective equipment firefighters	:		e, wear self-contained breathing apparatus. rective equipment.	
Sp od	pecific extinguishing meth- Is	:	cumstances and	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers.	



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		Remove und so. Evacuate are	lamaged containers from fire area if it is safe to do ea.		
SECTION	N 6: Accidental relea	ase measures			
6.1 Perso	nal precautions, prot	ective equipment a	and emergency procedures		
Personal precautions		Follow safe h	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).		
6.2 Enviro	onmental precautions	i			
Environmental precautions		Prevent furth Retain and d Local author	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.		
6.3 Metho	ds and material for c	ontainment and cl	eaning up		
Methods for cleaning up		tainer for dis Avoid disper- with compres Dust deposit es, as these leased into th Local or nation posal of this employed in mine which r Sections 13	sal of dust in the air (i.e., clearing dust surfaces		

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## **SECTION 7: Handling and storage**

### 7.1 Precautions for safe handling

:	Static electricity may accumulate and ignite suspended dust causing an explosion.
	Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
:	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
	:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Hygiene measures		sessment Minimize du Keep conta Keep away Take preca Take care t environmer If exposure flushing sys place. Whe	<ul> <li>Minimize dust generation and accumulation.</li> <li>Keep container closed when not in use.</li> <li>Keep away from heat and sources of ignition.</li> <li>Take precautionary measures against static discharges.</li> <li>Take care to prevent spills, waste and minimize release to the environment.</li> <li>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.</li> </ul>		
			re operation of a facility should include review of controls, proper personal protective equipment, degowning and decontamination procedures, /giene monitoring, medical surveillance and the nistrative controls.		
7.2 Cond	itions for safe storage,	, including any i	ncompatibilities		
	Requirements for storage areas and containers		perly labelled containers. Store in accordance with ar national regulations.		
Advi	Advice on common storage		e with the following product types: izing agents		
7.3 Specific end use(s) Specific use(s)		: No data ava	ailable		

## **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

dusts non-specific

#### **Occupational Exposure Limits**

4 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust) Basis: IE OEL

10 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust) Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Suvorexant	1030377- 33-3	TWA	14 μg/m3 (OEB 3)	Internal
		Wipe limit	140 µg/100 cm²	Internal
Magnesium stea- rate	557-04-0	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL



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#### 8.2 Exposure controls

#### **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

Eye/face 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.
Hand protection		
Material	:	Chemical-resistant gloves
Remarks Skin and body protection	:	Consider double gloving. Work uniform or laboratory coat. 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.
Respiratory protection Filter type	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143 Particulates type (P)

#### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic 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
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.



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	Flamm	ability (liquids)	:	No data available	9
		explosion limit / Upper ability limit	:	No data available	9
		explosion limit / Lower ability limit	:	No data available	9
	Flash p	point	:	Not applicable	
	Auto-ig	nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	рН		:	No data available	9
	Viscosi Visc	ity cosity, kinematic	:	Not applicable	
	Solubil Wat	ity(ies) ter solubility	:	No data available	9
	Partitio octano	n coefficient: n- I/water	:	Not applicable	
	Vapou	pressure	:	Not applicable	
	Relativ	e density	:	No data available	9
	Density	/	:	No data available	9
	Relativ	e vapour density	:	Not applicable	
		e characteristics ticle size	:	No data available	9
9.2		nformation			
	Explos		:	Not explosive	
		ng properties	:		r mixture is not classified as oxidizing.
	Evapor	ation rate	:	Not applicable	
	Molecu	ılar weight	:	No data available	9

Commission Regulation (EU) 2020/878



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### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions	<ul> <li>May form explosive dust-air mixture during processing, han- dling or other means.</li> <li>Can react with strong oxidizing agents.</li> </ul>
10.4 Conditions to avoid	
Conditions to avoid	: Heat, flames and sparks.

Conditions to avoid	. Tieat, liaities and spa	ain
	Avoid dust formation	۱.

#### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### **10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

#### **SECTION 11: Toxicological information**

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of	:	Inhalation
exposure		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

#### Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

### Suvorexant:

Species	:	Rabbit
Result	:	No skin irritation

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### Serious eye damage/eye irritation

Not classified based on available information.

#### **Components:**

#### Suvorexant:

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

#### 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

#### 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

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## Carcinogenicity

Not classified based on available information.

## Components:

Suvorexant:		
Species	:	Mouse
Application Route	:	Oral
Exposure time	:	6 month(s)
Result	:	negative
Species	:	Rat
Application Route	:	Oral
Exposure time	:	2 Years
Result	:	negative

#### **Reproductive toxicity**

Not classified based on available information.

## Components:

## Suvorexant:

Effects on fertility	: Test Type: Fertility/early embryonic development Species: Rat, male and female Application Route: Oral General Toxicity - Parent: NOAEL: >= 325 mg/kg body weight 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

#### 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.

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<u>Com</u>	ponents:		
Suvo	prexant:		
Targe	sure routes et Organs ssment	<ul> <li>Ingestion</li> <li>Central nervo</li> <li>May cause data</li> <li>exposure.</li> </ul>	ous system amage to organs through prolonged or repeated
Repe	eated dose toxicity		
<u>Com</u>	ponents:		
Suvo	prexant:		
Expo	EL	: Rat : 325 mg/kg : 1,200 mg/kg : Oral : 30 d : Blood, Pancr	eas
Expo	EL	: Dog : 50 mg/kg : 125 mg/kg : Oral : 30 d : Blood, Liver,	Central nervous system
Expo	EL	: Rat : 75 mg/kg : 300 mg/kg : Oral : 180 d : Pancreas, Bl	ood, Stomach
Expo	EL	: Dog : 50 mg/kg : 125 mg/kg : Oral : 270 d : Blood	
Expo	EL	: Rat : 40 mg/kg : 80 mg/kg : Oral : 18 Months : Eye, Central	nervous system

## Aspiration toxicity

Not classified based on available information.



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#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

#### Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### 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		

### **SECTION 12: Ecological information**

#### 12.1 Toxicity

#### 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)	:	1	
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	



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				Method: OECD T	est Guideline 209
	Toxicity to fish (Chronic tox- icity)		:	NOEC: 0.14 mg/l Exposure time: 32 Species: Pimepha Method: OECD T	ales promelas (fathead minnow)
6		to daphnia and other invertebrates (Chron- ty)	:	NOEC: 0.5 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211	
12.2	Persist	tence and degradabil	ity		
<u>(</u>	Compo	onents:			
5	Suvore	exant:			
E	Biodegı	radability	:	Result: Not readily Biodegradation: 8 Exposure time: 28 Method: OECD T	81 % 3 d
S	Stability	/ in water	:	Hydrolysis: < 10 % Method: OECD T	
12.3	Bioacc	umulative potential			
<u>(</u>	Compo	onents:			
5	Suvore	exant:			
E	Bioaccu	umulation	:	Species: Lepomis Bioconcentration Method: OECD T	
	Partition octanol	n coefficient: n- /water	:	log Pow: 4.04	
		r <b>y in soil</b> a available			
12.5	Result	s of PBT and vPvB as	sse	ssment	
F	Produc	: <u>t:</u>			
_	Assess		:	to be either persis	ixture contains no components considered stent, bioaccumulative and toxic (PBT), or ind very bioaccumulative (vPvB) at levels of
12.6	Endoc	rine disrupting prope	rtie	S	
Ē	Produc	<u>:t:</u>			
ļ	Assess	ment	:		ixture does not contain components consid- ocrine disrupting properties according to



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		REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.					
	<b>12.7 Other adverse effects</b> No data available						
SECTIO	N 13: Disposal cons	iderations					
13.1 Was	te treatment methods						
Product :		According to are not produ Waste codes discussion w	accordance with local regulations. the European Waste Catalogue, Waste Codes uct specific, but application specific. should be assigned by the user, preferably in ith the waste disposal authorities. se of waste into sewer.				
Cont	aminated packaging	: Empty conta dling site for	iners should be taken to an approved waste han- recycling or disposal. se specified: Dispose of as unused product.				

### **SECTION 14: Transport information**

## 14.1 UN number or ID number

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.2 UN proper shipping name		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.3 Transport hazard class(es)		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14 4 Packing group		

14.4 Packing group

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ADN		: Not regulated as a dangerous good	
ADR		: Not regulated as a dangerous good	
RID		: Not regulated as a dangerous good	
IMDG		: Not regulated as a dangerous good	
IATA (Cargo)		: Not regulated as a dangerous good	
IATA (Passenger)		: Not regulated as a dangerous good	
14.5 Envir	onmental hazards		
Not re	egulated as a dangero	s good	
14.6 Spec	ial precautions for us	er	
Not a	pplicable		
14.7 Marit	ime transport in bulk	according to IMO instruments	
Rema	arks	: Not applicable for product as supplied.	

## **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Seveso III: Directive 2012/18/ELL of the European Parlian	nent	and of the Council

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.



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SECTIO	N 16: Other information	on		
Othe	r information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.	
Full t	text of H-Statements			
H336	3	:	May cause drows	siness or dizziness.
H373	3	:		ge to organs through prolonged or repeated
H400	)	:	Very toxic to aqua	
H411		:	Toxic to aquatic li	ife with long lasting effects.
Full t	text of other abbreviation	ons		
Aqua	atic Acute	:	Short-term (acute	e) aquatic hazard
Aqua	atic Chronic	:	Long-term (chron	ic) aquatic hazard
STO	TRE	:	Specific target or	gan toxicity - repeated exposure
STO	T SE	:		gan toxicity - single exposure
IE OI	EL	:		nemical Agents and Carcinogens with Occu- e Limit Values - Code of Practice, Schedule 1
IE OI	EL / OELV - 8 hrs (TWA)	:	Occupational exp	osure limit value (8-hour reference period)
Wate	erways; ADR - Agreeme	ent	concerning the Int	tional Carriage of Dangerous Goods by Inland ernational Carriage of Dangerous Goods by nicals; ASTM - American Society for the Test-

Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -



## Suvorexant Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
2.3	28.09.2024	21538-00026	Date of first issue: 14.10.2014

Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Aquatic Chronic 3

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/
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Classification of	f the mixture:	
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H412

Calculation method

**Classification procedure:** 

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.

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