

Suvorexant Formulation

Version 9.0	Revision Date: 28.09.2024	SDS Numb 21524-000		
SECTION	1. IDENTIFICATION			
Produ	Product identifier		exant Formulation	
Manu	afacturer or supplier	's details		
Comp	bany	: MSD		
Addre	ess	nº 150	e Comendador Antônio Loureiro Rar 0 – Distrito Industrial s Claros – MG, Brazil 39404-620	nos,
Telep	phone	: +55 (3	8) 3229 7000	
Emer	gency telephone	: +55 (3	8) 3201 5670	
E-ma	il address	: EHSD	ATASTEWARD@msd.com	
Reco	mmended use of the	e chemical and	l restrictions on use	
	mmended use ictions on use	: Pharm : Not ap	aceutical plicable	
SECTION	2. HAZARDS IDENT			

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard				
:	Category 2			
:	Category 3			
ordan	ce with ABNT NBR 14725 Standard			
:	None			
:	H401 Toxic to aquatic life.			
	H412 Harmful to aquatic life with long lasting effects.			
:	Prevention:			
	P273 Avoid release to the environment.			
	: ordan :			

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components



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	nical name rexant	CAS-No. 1030377-33-3	Classification STOT SE, 3 STOT RE, (Oral)(Central nervous system), 2 Aquatic Acute, 1 Aquatic Chronic, 2	Concentration (% w/w) >= 5 -< 10
Magn	esium stearate	557-04-0		>= 1 -< 5

SECTION 4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air.
		Get medical attention if symptoms occur.
In case of skin contact	:	Wash with water and soap.
		Get medical attention if symptoms occur.
In case of eye contact	:	If in eyes, rinse well with water.
		Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting.
		Get medical attention if symptoms occur.
		Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and	:	Contact with dust can cause mechanical irritation or drying of the skin.
delayed		Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING 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.
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.



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				Remove undamaç so. Evacuate area.	ged containers from fire area if it is safe to do
		protective equipment ighters	:	In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.
SECT	ION 6.	ACCIDENTAL RELE	ASE	EMEASURES	
tiv	ve equ	al precautions, protec- ipment and emer- rocedures	:		ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).
E	nviron	mental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages
		s and materials for nent and cleaning up	:	container for disper Avoid dispersal of with compressed Dust deposits sho surfaces, as these released into the a Local or national r disposal of this ma employed in the c determine which r Sections 13 and 1	dust in the air (i.e., clearing dust surfaces

SECTION 7. HANDLING AND STORAGE

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion.
Local/Total ventilation	:	Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Use only with adequate ventilation.
Advice on safe handling		Do not breathe dust.
		Do not swallow.
		Avoid contact with eyes.
		Avoid prolonged or repeated contact with skin.
		Handle in accordance with good industrial hygiene and safety
		practice, based on the results of the workplace exposure
		assessment
		Minimize dust generation and accumulation.
		Keep container closed when not in use.
		Keep away from heat and sources of ignition.
		Take precautionary measures against static discharges.
		Take care to prevent spills, waste and minimize release to the



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Hygie	ene measures	flushing syst place. When using Wash contar The effective engineering appropriate o industrial hys	o chemical is likely during typical use, provide eye ems and safety showers close to the working do not eat, drink or smoke. ninated clothing before re-use. e operation of a facility should include review of controls, proper personal protective equipment, degowning and decontamination procedures, giene monitoring, medical surveillance and the histrative controls.
Cond	litions for safe storage		erly labeled containers. ordance with the particular national regulations.
Mate	rials to avoid		with the following product types:

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Suvorexant	1030377-33- 3	TWA	14 µg/m3 (OEB 3)	Internal
		Wipe limit	140 µg/100 cm ²	Internal
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH

Ingredients with workplace control parameters

Engineering measures	:	All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.		
Personal protective equipment				
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.		
Filter type Hand protection	:	Particulates type		
Material	:	Chemical-resistant gloves		
Pomarka		Consider double gloving		

Remarks : Consider double gloving.



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Еуе р	protection	If the work env mists or aeros Wear a facesh	lasses with side shields or goggles. vironment or activity involves dusty conditions, ols, wear the appropriate goggles. nield or other full face protection if there is a rect contact to the face with dusts, mists, or
Skin	and body protection	Additional bod task being per disposable sui	or laboratory coat. y garments should be used based upon the formed (e.g., sleevelets, apron, gauntlets, ts) to avoid exposed skin surfaces. te degowning techniques to remove potentially clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	powder
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	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, handling 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
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available



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octan Autoig	Partition coefficient: n- octanol/water Autoignition temperature Decomposition temperature		Not applicable No data available No data available	
	scosity, kinematic	:	Not applicable	
Explo	Explosive properties		Not explosive	
	zing properties sular weight	:	The substance o	r mixture is not classified as oxidizing. e
	le characteristics le size	:	No data available	e

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials Hazardous decomposition products	:	Oxidizing agents

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
Acute toxicity		
Not classified based on availa	ble	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:



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Acute	e oral toxicity	Method: O Assessme icity	e: > 2.000 mg/kg ECD Test Guideline 423 nt: The substance or mixture has no acute oral tox- Based on data from similar materials
Acute	e dermal toxicity		bit): > 2.000 mg/kg Based on data from similar materials
-	corrosion/irritation	able information	
	ponents:		
	prexant:		
		: Rabbit	
Spec Resu		: No skin irr	tation
Magr	nesium stearate:		
Spec		: Rabbit	
Resu		: No skin irr	
Rema	arks	: Based on	data from similar materials
Not c	ous eye damage/eye ir classified based on avail ponents:		
Suvo	prexant:		
Spec		: Bovine co	
Resu Meth		: Mild eye ir	ritation nea (BCOP)
	nesium stearate:		
Spec		: Rabbit	ation.
Resu Rema		: No eye irri : Based on	data from similar materials
Poer	piratory or skin sensiti	zation	
-	-	zation	
_	sensitization lassified based on avail	able information	
Resp	biratory sensitization		
-	lassified based on avail	able information	
	ponents:		
	prexant:		
Test		· Local lymr	h node assay (LLNA)
Spec		: Mouse	
Asse	ssment		ause skin sensitization.
Resu	llt	: negative	

- Does not cause skin sensitization.negative



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ersion .0	Revision Date: 28.09.2024	SDS Numbe 21524-0002	
Test	es of exposure les od lt	: Skin cor : Guinea : OECD T : negative	pig Test Guideline 406
	cell mutagenicity lassified based on ava	ailable informati	n
_	ponents:		
Suvo	rexant:		
Genotoxicity in vitro			be: Bacterial reverse mutation assay (AMES) negative
		Test sys	be: Alkaline elution assay stem: rat hepatocytes negative
		Test sys	be: Chromosomal aberration stem: Chinese hamster ovary cells negative
Geno	toxicity in vivo	Species	be: Micronucleus test : Mouse negative
		Species	be: Micronucleus test : Rat negative
Magn	esium stearate:		
Geno	toxicity in vitro	Result:	be: In vitro mammalian cell gene mutation test negative s: Based on data from similar materials
		Method: Result:	be: Chromosome aberration test in vitro OECD Test Guideline 473 negative s: Based on data from similar materials
		Result:	be: Bacterial reverse mutation assay (AMES) negative s: Based on data from similar materials

Carcinogenicity

Not classified based on available information.



ersion D	Revision Date: 28.09.2024		S Number: 524-00025	Date of last issue: 26.09.2023 Date of first issue: 14.10.2014
Comp	oonents:			
Suvo	rexant:			
	cation Route sure time	:	Mouse Oral 6 month(s) negative	
Speci			Rat	
Applic	cation Route sure time	: :	Oral 2 Years negative	
-	oductive toxicity			
	assified based on availa conents:	able	information.	
Suvo	rexant:			
	s on fertility	:	Species: Rat, I Application Ro	ty Parent: NOAEL: >= 325 mg/kg body weigh
Effect	s on fetal development	:	Species: Rabb Application Ro	ute: Oral I Toxicity: NOAEL: 150 mg/kg body weight
			Species: Rat Application Ro	I Toxicity: NOAEL: 80 mg/kg body weight
Magn	esium stearate:			
	s on fertility	:	reproduction/d Species: Rat Application Ro Method: OECI Result: negativ) Test Guideline 422
Effect	s on fetal development	:	Species: Rat Application Ro Result: negative	



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STO	Γ-single exposure		
Not c	lassified based on av	ailable information.	
Com	ponents:		
Suvo	erexant:		
Rema		: Based on hu	man experience.
STO	F-repeated exposure	•	
	lassified based on av		
<u>Com</u>	ponents:		
Suvo	erexant:		
	es of exposure	: Ingestion	
	et Organs	: Central nervo	
Asses	ssment	exposure.	amage to organs through prolonged or repeated
Repe	ated dose toxicity		
Com	ponents:		
Suvo	rexant:		
Spec		: Rat	
NOA		: 325 mg/kg	
LOAE	∠ cation Route	: 1.200 mg/kg : Oral	
	sure time	: 30 d	
	et Organs	: Blood, Pancr	eas
Spec		: Dog	
NOA		: 50 mg/kg	
LOAE	□∟ cation Route	: 125 mg/kg : Oral	
	sure time	: 30 d	
	et Organs		Central nervous system
Spec	ies	: Rat	
NOA		: 75 mg/kg	
LOAE		: 300 mg/kg	
	cation Route sure time	: Oral : 180 d	
	et Organs		ood, Stomach
Spec		: Dog	
NOA		: 50 mg/kg	
LOAE	∠ cation Route	: 125 mg/kg : Oral	
	sure time	: 270 d	
	et Organs	: Blood	
Spec		: Rat	
NOAI LOAE		: 40 mg/kg : 80 mg/kg	
		. 00 mg/kg	



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Expo	cation Route sure time et Organs	: Oral : 18 Months : Eye, Central nervous syster	n
Spec NOA Appli	EL cation Route sure time	 Rat > 100 mg/kg Ingestion 90 Days Based on data from similar 	materials
Not c	ration toxicity lassified based on ava rience with human e		
	ponents:		
	prexant: stion	tigue, Dizziness, dry mouth,	adache, abnormal dreams, Fa- Nausea, liver function change, tion, urinary tract infection, Cough, cardia
SECTION	12. ECOLOGICAL IN	ORMATION	
Ecot	oxicity		
Com	ponents:		

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 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



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ersion 0	Revision Date: 28.09.2024		DS Number: 524-00025	Date of last issue: 26.09.2023 Date of first issue: 14.10.2014
Toxicity to microorganisms :		:	EC50: > 1.000 m Exposure time: 3 Test Type: Respi Method: OECD T	ĥ
			NOEC: 1.000 mg Exposure time: 3 Test Type: Respi Method: OECD T	h
Magr	esium stearate:			
Toxic	ity to fish	:	Exposure time: 4 Method: DIN 384	
	ity to daphnia and other ic invertebrates	:	Exposure time: 4 Test substance: 1 Method: Directive	Water Accommodated Fraction e 67/548/EEC, Annex V, C.2. on data from similar materials
Toxic plants	ity to algae/aquatic	:	mg/l Exposure time: 7 Test substance: 1 Method: OECD T	Nater Accommodated Fraction est Guideline 201 on data from similar materials
			mg/l Exposure time: 7 Test substance: \ Method: OECD T	kirchneriella subcapitata (green algae)): > 1 2 h Water Accommodated Fraction est Guideline 201 on data from similar materials
Toxic	ity to microorganisms	:	Exposure time: 1 Test substance: \	onas putida): > 100 mg/l 6 h Nater Accommodated Fraction on data from similar materials
Persi	stence and degradabil	ity		
<u>Com</u>	oonents:			
	rexant:			
Biode	gradability	:	Result: Not readil Biodegradation: Exposure time: 2	81 %

Method: OECD Test Guideline 314



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Stabilit	Stability in water		drolysis: < 10 thod: OECD) %(5 d) Test Guideline 111
Magne	esium stearate:			
	Biodegradability		sult: Not bioc marks: Base	legradable d on data from similar materials
Bioac	cumulative potential			
Comp	onents:			
Suvor	exant:			
Bioaco	cumulation	Bio	concentratio	nis macrochirus (Bluegill sunfish) n factor (BCF): 358 Test Guideline 305
	Partition coefficient: n- octanol/water		Pow: 4,04	
Magne	esium stearate:			
Partitic octanc	on coefficient: n- bl/water	: log	Pow: > 4	
Mobili	ty in soil			
No dat	a available			
Other adverse effects				
No data available				

SECTION 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 handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation



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ANTT Not re	r egulated as a dangero	ous good							
	Special precautions for user Not applicable								
SECTION 15. REGULATORY INFORMATION									
		onmental regulations/	legislation specific for the substance or						
mixtu	ire								
	nal List of Carcinoger	nic Agents for Humans	- : Not applicable						
Natio (LINA	nal List of Carcinoger CH) . List of chemicals co	nic Agents for Humans							
Nation (LINA Brazil Police	nal List of Carcinoger CH) I. List of chemicals co	ntrolled by the Federal							
Nation (LINA Brazil Police	nal List of Carcinoger CH) I. List of chemicals co	ntrolled by the Federal	: Not applicable n the following inventories:						
Nation (LINA Brazil Police The i	nal List of Carcinoger CH) I. List of chemicals co	ntrolled by the Federal	: Not applicable n the following inventories:						

SECTION 16. OTHER INFORMATION

Revision Date	:	28.09.2024
Date format	:	dd.mm.yyyy

Further information

Sources of key data used to	:	Internal technical data, data from raw material SDSs, OECD
compile the Material Safety		eChem Portal search results and European Chemicals Agen-
Data Sheet		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.

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 con-



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centration; 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 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 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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