

according to GB/T 16483 and GB/T 17519

Mirtazapine Solid Formulation

Version 4.10	Revision Date: 2020/03/23		S Number: 56-00015	Date of last issue: 2019/09/13 Date of first issue: 2015/01/23	
1. PRODUCT AND COMPANY IDENT Product name :			IFICATION Mirtazapine Solid	d Formulation	
-	nufacturer or supplier's npany	detai :	ls Organon & Co.		
Add	Iress	:	30 Hudson Stree Jersey City, New	et, 33nd floor 9 Jersey, U.S.A 07302	
Tele	ephone	:	551-430-6000		
Eme	ergency telephone numb	er :	215-631-6999		
E-m	ail address	:	EHSSTEWARD	@organon.com	
Recommended use of the chemical and restrictions on use					

2. HAZARDS IDENTIFICATION

Recommended use

Emergency Overview

Appearance Colour	: powder : No data available
Odour	: No data available
May be harmful if swal	lowed. Suspected of damaging fertility. Suspected of dama

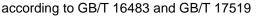
: Pharmaceutical

May be harmful if swallowed. Suspected of damaging fertility. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure. Harmful to aquatic life with long lasting effects.

GHS Classification

Acute toxicity (Oral)	:	Category 5
Reproductive toxicity	:	Category 2
Specific target organ toxicity - repeated exposure	:	Category 2
Short-term (acute) aquatic hazard	:	Category 3
Long-term (chronic) aquatic hazard	:	Category 3
GHS label elements Hazard pictograms	:	







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Signal	word	: Warning			
Hazard statements		H361fd Susp ing the unbor H373 May ca peated expos	H303 May be harmful if swallowed. H361fd Suspected of damaging fertility. Suspected of damag- ing the unborn child. H373 May cause damage to organs through prolonged or re- peated exposure. H412 Harmful to aquatic life with long lasting effects.		
Precautionary statements		P202 Do not and understo P260 Do not P273 Avoid r	breathe dust. elease to the environment. rotective gloves/ protective clothing/ eye protec-		
		Response: P312 Call a F	Response: P312 Call a POISON CENTER/ doctor if you feel unwell.		
		Storage: P405 Store lo	ocked up.		
		Disposal: P501 Dispos disposal plan	e of contents/ container to an approved waste t.		

Physical and chemical hazards

Not classified based on available information.

Health hazards

May be harmful if swallowed. Suspected of damaging fertility. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.

Environmental hazards

Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

Other hazards which do not result in classification

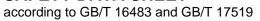
Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

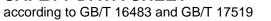
Components

Chemical name	CAS-No.	Concentration (% w/w)
(+/-)-1,2,3,4,10,14b-Hexahydro-2- methylpyrazino[2,1-a]pyrido[2,3- c][2]benzazepine	85650-52-8	>= 10 -< 20
Starch	9005-25-8	>= 10 -< 20





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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.
In case of skin contact	 Get medical attention. In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
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. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	 May be harmful if swallowed. Suspected of damaging fertility. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure. Contact with dust can cause mechanical irritation or drying of the skin.
Protection of first-aiders	 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).
Notes to physician	: Treat symptomatically and supportively.
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.
Hazardous combustion prod- ucts	: Carbon oxides Silicon 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.
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		protective equipment ghters	:	Evacuate area. In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.
6. AC(ITAL RELEASE MEAS	SUF	RES	
Personal precautions, protec- tive equipment and emer- gency procedures		:	Use personal protective equipment. Follow safe handling advice and personal protective equip- ment recommendations.		
E	Inviron	mental precautions	:	Prevent further lea Retain and dispos	e environment must be avoided. akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages ed.
		ls and materials for ment and cleaning up	:	tainer for disposal Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the atr Local or national r posal of this mate employed in the c mine which regula Sections 13 and 1	dust in the air (i.e., clearing dust surfaces

7. HANDLING AND STORAGE

Handling		
Technical measures	causir Provid	electricity may accumulate and ignite suspended dust g an explosion. e adequate precautions, such as electrical grounding onding, or inert atmospheres.
Local/Total ventilation Advice on safe handling Avoidance of contact	Use o Do no Do no Avoid Handle practic sessm Minim Keep Take p Take p Take p	hly with adequate ventilation. t breathe dust. t swallow. contact with eyes. prolonged or repeated contact with skin. e in accordance with good industrial hygiene and safety ce, based on the results of the workplace exposure as- nent ize dust generation and accumulation. container closed when not in use. away from heat and sources of ignition. precautionary measures against static discharges. care to prevent spills, waste and minimize release to the nment.
Avoluance of contact	Oxiuiz	ing agents





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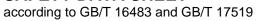
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Stora	age				
Conditions for safe storage		:	Store locked u	y labelled containers. ance with the particular national regula	ations.
Materials to avoid		:		th the following product types:	
Packaging material		:	Unsuitable ma	erial: None known.	

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
(+/-)-1,2,3,4,10,14b- Hexahydro-2- methylpyrazino[2,1- a]pyrido[2,3-c][2]benzazepine	85650-52-8	TWA	25 µg/m3	Internal
		Wipe limit	250 µg/100 cm ²	Internal
Starch	9005-25-8	TWA	10 mg/m3	ACGIH

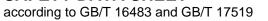
Engineering measures	Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are de- signed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
Personal protective equipment	t
Respiratory protection	sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type	Particulates type
Eye/face protection	Wear the following personal protective equipment: Safety goggles
Skin and body protection	Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Hand protection	
Material	Chemical-resistant gloves
Remarks	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the





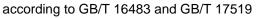


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	Hygiene measures		 end of workday. If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. 			
9. PHY	SICAL AND CHEMICAL PI	ROP	ERTIES			
Ар	pearance	:	powder			
Co	lour	:	No data available	9		
Od	lour	:	No data available	9		
Od	lour Threshold	:	No data available	9		
рH		:	No data available	9		
Me	elting point/freezing point	:	No data available	9		
	tial boiling point and boiling nge	:	No data available	9		
Fla	ash point	:	Not applicable			
Ev	aporation rate	:	No data available	9		
Fla	ammability (solid, gas)	:	May form explosi dling or other me	ive dust-air mixture during processing, han- ans.		
Fla	ammability (liquids)	:	No data available	9		
•	per explosion limit / Upper mmability limit	:	No data available	9		
	wer explosion limit / Lower mmability limit	:	No data available	2		
Va	pour pressure	:	No data available	9		
Re	lative vapour density	:	No data available	9		
Re	lative density	:	No data available	9		
De	nsity	:	No data available	9		
So	lubility(ies) Water solubility	:	No data available	9		
	rtition coefficient: n-	:	No data available	9		
	tanol/water to-ignition temperature	:	No data available	9		





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Decor	mposition temperature	:	No data available		
Visco: Vis	sity scosity, dynamic	:	No data available		
Vis	scosity, kinematic	:	No data available		
Explo	sive properties	:	Not explosive		
Oxidiz	zing properties	:	The substance or	mixture is not classified as oxidizing.	
Molec	ular weight	:	No data available		
Partic	le size	:	No data available		
0. STABI	LITY AND REACTIVITY	(
	ivity ical stability bility of hazardous reac-	:	Stable under norr May form explosi dling or other me	ve dust-air mixture during processing, han-	
Condi	tions to avoid		: Heat, flames and sparks.		
	patible materials dous decomposition cts	:	Avoid dust formation.Oxidizing agentsNo hazardous decomposition products are known.		
1. TOXIC	OLOGICAL INFORMAT	ΓΙΟΝ			
Expos	sure routes	: 	nhalation Skin contact ngestion Eye contact		
	toxicity he harmful if swallowed.				
<u>Produ</u> Acute	<u>ict:</u> oral toxicity		Acute toxicity estimate: 3,200 mg/kg Method: Calculation method		
<u>Comp</u>	oonents:				
• •	, 2,3,4,10,14b-Hexahyd oral toxicity		methylpyrazino[ź ₋D50 (Rat): 320 -	2,1-a]pyrido[2,3-c][2]benzazepine: 490 mg/kg	
Starc Acute	h: oral toxicity	: [_D50 (Rat): > 5,00)0 mg/kg	
Acuto	dermal toxicity	: 1	: LD50 (Rabbit): > 2,000 mg/kg		





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Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation Not classified based on available information.

Components:

Starch:

Species	
Result	

RabbitNo eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Starch:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:

Genotoxicity in vitro :	Test Type: Bacterial reverse mutation assay (AMES) Result: negative				
	Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster lung cells Result: negative				
	Test Type: unscheduled DNA synthesis assay Test system: mammalian cells Result: negative				
	Test Type: sister chromatid exchange assay Test system: mammalian cells Result: negative				
Genotoxicity in vivo :	Test Type: Micronucleus test Species: Rat Cell type: Bone marrow Application Route: Oral				



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		Result: nega	ative
Starcl	h:		
Genot	oxicity in vitro	: Test Type: E Result: nega	Bacterial reverse mutation assay (AMES) ative
	n ogenicity assified based on ava	ilable information.	
<u>Comp</u>	oonents:		
(+/-)-1	,2,3,4,10,14b-Hexah	/dro-2-methylpyra	zino[2,1-a]pyrido[2,3-c][2]benzazepine:
Expos LOAE Result	ation Route sure time L	: Mouse : Oral : 18 month(s) : 200 mg/kg b : equivocal : Liver	
Expos LOAE Result	ation Route sure time L	: Rat : Oral : 2 Years : 20 mg/kg bc : equivocal : Liver, Thyro	
Repro	oductive toxicity		
		ility. Suspected of o	damaging the unborn child.
<u>Comp</u>	oonents:		
			zino[2,1-a]pyrido[2,3-c][2]benzazepine:
Effects	s on fertility	Species: Ra Application I Fertility: LO/ Symptoms: tions Result: Anin	
Effects ment	s on foetal develop-	Species: Ra Application I Developmer Result: Emb spring were	Route: Oral ntal Toxicity: LOAEL: 100 mg/kg body weight oryotoxic effects and adverse effects on the off- detected., No teratogenic effects
		Species: Ra Application	



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ersion .10	Revision Date: 2020/03/23	SDS Number: 50156-00015	Date of last issue: 2019/09/13 Date of first issue: 2015/01/23
		Result: No ac	dverse effects, No teratogenic effects
Repro sessr	oductive toxicity - As- nent	fertility, base	ice of adverse effects on sexual function and d on animal experiments., Some evidence of cts on development, based on animal experi-
	Γ - single exposure lassified based on ava	ilable information.	
	F - repeated exposure cause damage to orga		d or repeated exposure.
Com	ponents:		
(+/-)-′	1,2,3,4,10,14b-Hexahy	dro-2-methylpyraz	zino[2,1-a]pyrido[2,3-c][2]benzazepine:
•	sure routes	: Ingestion	·

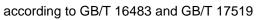
Exposure routes	: Ingestion
Target Organs	: Nervous system
Assessment	: May cause damage to organs through prolonged or repeated
	exposure.

Repeated dose toxicity

Components:

(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:

Species LOAEL Application Route Exposure time Target Organs	 Rat 120 mg/kg Oral 13 Weeks Nervous system
Species LOAEL Application Route Exposure time Target Organs Symptoms	 Dog 15 mg/kg Oral 52 Weeks Nervous system Tremors
Species LOAEL Application Route Exposure time Target Organs Symptoms	 Dog 20 mg/kg Oral 13 Weeks Nervous system, Testis Tremors
Starch: Species NOAEL Application Route Exposure time Method	 Rat >= 2,000 mg/kg Skin contact 28 Days OECD Test Guideline 410





/ersion I.10	Revision Date: 2020/03/23		OS Number: 156-00015	Date of last issue: 2019/09/13 Date of first issue: 2015/01/23
-	ation toxicity lassified based on availa	able	information.	
Expe	rience with human exp	osi	ıre	
<u>Com</u>	oonents:			
(+/-)- 1	I,2,3,4,10,14b-Hexahyd	ro-2	2-methylpyrazino	[2,1-a]pyrido[2,3-c][2]benzazepine:
Inges	tion	:	Symptoms: Drow Dizziness, Disorie	siness, constipation, dry mouth, asthenia, entation
2. ECOL	OGICAL INFORMATION	N		
Ecoto	oxicity			
Com	oonents:			
	I,2,3,4,10,14b-Hexahyd ity to fish	lro-2		
	ity to daphnia and other ic invertebrates	:	EC50 (Daphnia n Exposure time: 4	nagna (Water flea)): 19.5 mg/l 8 h
Toxici plants	ity to algae/aquatic	:	mg/l Exposure time: 72	chneriella subcapitata (green algae)): 5.7 2 h est Guideline 201
			mg/l Exposure time: 72	rchneriella subcapitata (green algae)): 3.2 2 h est Guideline 201
Toxici icity)	ity to fish (Chronic tox-	:	Exposure time: 3	es promelas (fathead minnow)): 3.6 mg/l 1 d est Guideline 210
	ity to daphnia and other ic invertebrates (Chron- icity)	:	Exposure time: 2	magna (Water flea)): 0.32 mg/l 1 d est Guideline 211
Toxic	ity to microorganisms	:	Exposure time: 3 Test Type: Respi	
			Exposure time: 3 Test Type: Respi	



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	stence and degradal	bility		
Bioad	ccumulative potentia	I		
<u>Com</u>	ponents:			
(+/-)-^	1,2,3,4,10,14b-Hexah	ydro-2	-methylpyrazi	no[2,1-a]pyrido[2,3-c][2]benzazepine:
Bioac	cumulation	:	Bioconcentrati	orhynchus mykiss (rainbow trout) on factor (BCF): 334 D Test Guideline 305
	ion coefficient: n- ol/water	:	log Pow: 2.78	
Mobi	lity in soil			
<u>Com</u>	ponents:			
Distril menta Othe	bution among environ- al compartments r adverse effects ata available	-	log Koc: 4.48	no[2,1-a]pyrido[2,3-c][2]benzazepine:
3. DISPC	SAL CONSIDERATION	ONS		
Disno	osal methods			
Waste	e from residues aminated packaging	:	Empty contain dling site for re	accordance with local regulations. ers should be taken to an approved waste han- ecycling or disposal. e specified: Dispose of as unused product.
4. TRAN	SPORT INFORMATIC	ON		
Interr	national Regulations			
UNR Not re	TDG egulated as a dangero	ous goo	d	
IATA Not re	-DGR egulated as a dangero	ous goo	d	
-	-Code egulated as a dangero	ous goo	d	
	sport in bulk accordi pplicable for product a	-		RPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

GB 6944/12268

Not regulated as a dangerous good

Special precautions for user

Not applicable



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15. REGULATORY INFORMATION

National regulatory information Law on the Prevention and Control of Occupational Diseases

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

16. OTHER INFORMATION

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	:	yyyy/mm/dd		
Full text of other abbreviations				
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)		
ACGIH / TWA	:	8-hour, time-weighted average		

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect 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, Evalua-



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tion, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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

Disclaimer

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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