

according to Regulation (EC) No. 1907/2006

Mirtazapine Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 13.09.2019
4.3	23.03.2020	51093-00015	Date of first issue: 23.01.2015

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

1.1 Product identifier

Trade name : Mirtazapine Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company	:	Organon & Co. Shotton Lane NE23 3JU Cramlington NU - Great Britain
Telephone	:	44 1 670 59 30 00
E-mail address of person responsible for the SDS	:	EHSSTEWARD@organon.com

1.4 Emergency telephone number

215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 2	H361fd: Suspected of damaging fertility. Suspected
	of damaging the unborn child.
Specific target organ toxicity - repeated	H373: May cause damage to organs through pro-
exposure, Category 2	longed or repeated exposure.
Long-term (chronic) aquatic hazard, Cat-	H412: Harmful to aquatic life with long lasting ef-
egory 3	fects.
l abol olomonts	

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

Signal word :		Warning
Hazard statements :	:	 H361fd Suspected of damaging fertility. Suspected of damaging the unborn child. H373 May cause damage to organs through prolonged or repeated exposure. H412 Harmful to aquatic life with long lasting effects.

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Preca	autionary statements	P260 Do not P273 Avoid re	special instructions before use. breathe dust. elease to the environment. rotective gloves/ protective clothing/ eye protec- ction.
		Response: P308 + P313 attention.	IF exposed or concerned: Get medical advice/
		Storage: P405 Store lo	ocked up.

Hazardous components which must be listed on the label:

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

2.3 Other hazards

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

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
(+/-)-1,2,3,4,10,14b-Hexahydro-2- methylpyrazino[2,1-a]pyrido[2,3- c][2]benzazepine	85650-52-8 288-060-6	Acute Tox. 4; H302 Repr. 2; H361fd STOT RE 2; H373 Aquatic Chronic 2; H411	>= 10 - < 20

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).
If inhaled	:	If inhaled, remove to fresh air.



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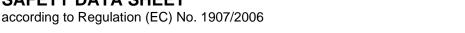
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				Get medical atten	tion.
Ir	n case	of skin contact	:	of water. Remove contamin Get medical atten Wash clothing be	
Ir	n case	of eye contact	:	lf in eyes, rinse w Get medical atten	ell with water. tion if irritation develops and persists.
lf	fswall	owed	:	Get medical atten	NOT induce vomiting. tion. oughly with water.
4.2 Mo	ost im	portant symptoms a	nd e	effects, both acute	and delayed
R	Risks		:	unborn child.	naging fertility. Suspected of damaging the ge to organs through prolonged or repeated
				the skin.	can cause mechanical irritation or drying of the eyes can lead to mechanical irritation.
4.3 In	dicati	on of any immediate	mee	dical attention and	special treatment needed
Т	reatm	ent	:	Treat symptomati	cally and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
5.2 Special hazards arising from	the	e substance or mixture
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





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5.3 Advice for firefighters	
 Special protective equipment for firefighters In the event of fire, wear self-contained breathing appart Use personal protective equipment. Specific extinguishing methods Use extinguishing measures that are appropriate to loc cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is sa so. Evacuate area. 	al cir-

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

en i electia precadició, preces		equipment and entergency precedures
Personal precautions		Use personal protective equipment. Follow safe handling advice and personal protective equip- ment recommendations.
6.2 Environmental precautions		
Environmental precautions		Discharge into the environment must be avoided. 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 Methods and material for co	ntain	ment and cleaning up
Methods for 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 surfac- es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and dis- posal 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.

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

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.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

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Ac	ocal/Total ventilation dvice on safe handling	 Do not bre Do not sw Avoid con Avoid prol Handle in practice, b sessment Minimize of Keep cont Keep awa Take prec Take care environme If exposur flushing sy place. Wh 	allow. tact with eyes. onged or repeated contact with skin. accordance with good industrial hygiene and safety based on the results of the workplace exposure as- dust generation and accumulation. ainer closed when not in use. y from heat and sources of ignition. autionary measures against static discharges. to prevent spills, waste and minimize release to the
7.2 Co	nditions for safe storage,	including any	incompatibilities
	equirements for storage eas and containers		roperly labelled containers. Store locked up. Store in ce with the particular national regulations.
Ad	dvice on common storage		pre with the following product types: idizing agents
•	ecific end use(s) becific use(s)	: No data a	vailable

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Starch	9005-25-8	TWA (inhalable dust)	10 mg/m3	GB EH40
	halable dust a sampling is ur MDHS14/4 G ble, thoracic a hazardous to in air equal to mg.m-3 8-hou ject to COSHI have been as the appropriat of sizes. The entry into the	The those fractions of indertaken in accordate eneral methods for so and inhalable aeroso health includes dust or greater than 10 m or TWA of respirable H if people are exposisioned specific WEL re limits., Most indust behaviour, deposition human respiratory so	ses of these limits, respirable airborne dust which will be c ince with the methods descril ampling and gravimetric ana ls, The COSHH definition of a of any kind when present at ng.m-3 8-hour TWA of inhala dust. This means that any du sed to dust above these level s and exposure to these must trial dusts contain particles of n and fate of any particular pay ystem, and the body respons the particle. HSE distinguishe	collected when bed in lysis or respira- a substance a concentration ble dust or 4 ust will be sub- s. Some dusts st comply with f a wide range article after e that it elicits,



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		ble dust appro and mouth du respiratory tra to the gas exc material are g their own ass Where no spe	oximates to the fraction oximates to the fraction oxing breathing and is act. Respirable dust a change region of the piven in MDHS14/4., igned WEL, all the re	termed 'inhalable' and 'r on of airborne material t approximates to the fract lung. Fuller definitions a Where dusts contain cor elevant limits should be o osure limit is listed, a figure used.	hat enters the nose deposition in the tion that penetrates nd explanatory mponents that have complied with.,	
			TWA (Respirable dust)	4 mg/m3	GB EH40	
Hexa methy zino[2 a]pyri	4,10,14b- hydro-2- /lpyra- 2,1- do[2,3- enzazepine	85650-52-8	TWÁ	25 μg/m3	Internal	
			Wipe limit	250 µg/100 cm ²	Internal	
Silica		71187-19-4	TWA (inhalable dust)	6 mg/m3 (Silica)	GB EH40	
		halable dust a sampling is un MDHS14/4 G ble, thoracic a hazardous to in air equal to mg.m-3 8-hou ject to COSHI have been as the appropriat of sizes. The entry into the depend on the fractions for li ble dust appro- and mouth du respiratory tra- to the gas exc material are g their own assi-	are those fractions of indertaken in accorda eneral methods for s and inhalable aeroso health includes dust or greater than 10 m ur TWA of respirable H if people are exposision signed specific WEL te limits., Most indus behaviour, deposition human respiratory s e nature and size of mit-setting purposes oximates to the fraction act. Respirable dust a change region of the given in MDHS14/4., igned WEL, all the re ecific short-term expo- posure limit should be		be collected when escribed in analysis or respira- n of a substance nt at a concentration halable dust or 4 ny dust will be sub- levels. Some dusts must comply with es of a wide range lar particle after ponse that it elicits, uishes two size respirable'., Inhala- hat enters the nose deposition in the tion that penetrates nd explanatory mponents that have complied with., are three times the	
			TWA (Respirable dust)	2.4 mg/m3 (Silica)	GB EH40	

8.2 Exposure controls

Engineering measures

Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions.



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cessii		signed in a manner	chaust ducts, dust collectors, vessels, and pro- to prevent the escape of dust into the work area		
Perso	onal protective equip	ment			
Eye p	protection	Safety gogg	llowing personal protective equipment: les should conform to BS EN 166		
Hand	protection	Equipment			
Ma	aterial	: Chemical-re	sistant gloves		
Re	emarks	on the conc stance and determined applications chemicals o	ves to protect hands against chemicals depending entration and quantity of the hazardous sub- specific to place of work. Breakthrough time is not for the product. Change gloves often! For special , we recommend clarifying the resistance to f the aforementioned protective gloves with the facturer. Wash hands before breaks and at the day.		
Skin a	and body protection	: Select appro resistance o potential. Skin contac	Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure		
Respi	iratory protection	: If adequate sure assess ommended	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 BS EN 143		
Filter	type	: Particulates			

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold	: : :	powder No data available No data available 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	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Upper explosion limit / Upper flammability limit	:	No data available





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		explosion limit / Lower bility limit	:	No data available	9
	Vapou	pressure	:	No data available)
	Relativ	e vapour density	:	No data available	2
	Relativ	e density	:	No data available)
	Density	1	:	No data available)
	Partitio octano	er solubility n coefficient: n- /water	:	No data available No data available	
	-	nition temperature	:	No data available	
		position temperature	:	No data available	3
	Viscosi Visc	ty cosity, dynamic	:	No data available)
	Viso	cosity, kinematic	:	No data available	9
	Explos	ve properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
9.2	Other ir	nformation			
	Flamm	ability (liquids)	:	No data available	9
	Molecu	lar weight	:	No data available	9
	Particle	e size	:	No data available	9

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

- Conditions to avoid : Heat, flames and span Avoid dust formation.
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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 toxicological effects

Information on likely routes of : Inhalation exposure Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg
		Method: Calculation method

Components:

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

-			
Acute	oral	toxicity	
Acuto	orai	lovicity	

: LD50 (Rat): 320 - 490 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

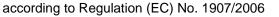
Not classified based on available information.

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





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		Result: negative	
		Test Type: unsch Test system: man Result: negative	eduled DNA synthesis assay nmalian cells
		Test Type: sister Test system: man Result: negative	chromatid exchange assay nmalian cells
Genoto	oxicity in vivo	: Test Type: Micror Species: Rat Cell type: Bone m Application Route Result: negative	arrow

Carcinogenicity

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:

Species Application Route Exposure time LOAEL Result Target Organs	· · · · · · · · · · · · · · · · · · ·	Mouse Oral 18 month(s) 200 mg/kg body weight equivocal Liver
Species Application Route Exposure time LOAEL Result Target Organs	: : : : : : : : : : : : : : : : : : : :	Rat Oral 2 Years 20 mg/kg body weight equivocal Liver, Thyroid

Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:

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

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Oral Fertility: LOAEL: 15 mg/kg body weight Symptoms: Effect on estrous cycle, Increase of early resorp- tions Result: Animal testing did not show any effects on fertility., Embryotoxic effects and adverse effects on the offspring were detected.
Effects on foetal develop-	:	Test Type: Development

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ment		Result: Embryoto spring were detec Test Type: Devel Species: Rabbit Application Route Developmental Te	oxicity: LOAEL: 100 mg/kg body weight xic effects and adverse effects on the off- cted., No teratogenic effects opment
Repro sessn	ductive toxicity - As- nent	fertility, based on	f adverse effects on sexual function and animal experiments., Some evidence of n development, based on animal experi-

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

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

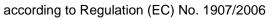
Exposure routes	: Ingestion
Target Organs	: Nervous system
Assessment	: May cause damage to organs through prolonged or repeated
	exposure.

Repeated dose toxicity

Components:

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

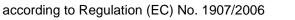
Species LOAEL Application Route Exposure time Target Organs	:	Rat 120 mg/kg Oral 13 Weeks Nervous system
Species LOAEL Application Route Exposure time Target Organs Symptoms	:	Dog 15 mg/kg Oral 52 Weeks Nervous system Tremors
Species LOAEL Application Route Exposure time Target Organs	::	Dog 20 mg/kg Oral 13 Weeks Nervous system, Testis





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Sympto	oms	:	Tremors			
-	tion toxicity ssified based on availa	ıble	information.			
Experi	ence with human exp	osu	re			
Comp	onents:					
(+/-)-1, Ingesti	· · · · ·	ro-2		no[2,1-a]pyrido[2,3-c][2]benzazepine: owsiness, constipation, dry mouth, asthenia, prientation		
ECTION 2.1 Toxici	12: Ecological infor	ma	tion			
	onents:					
		ro-2	-methylpyrazir	no[2,1-a]pyrido[2,3-c][2]benzazepine:		
	y to fish	:		ales promelas (fathead minnow)): 6.92 mg/l : 96 h		
	y to daphnia and other invertebrates	:	EC50 (Daphnia magna (Water flea)): 19.5 mg/l Exposure time: 48 h			
Toxicit <u>y</u> plants	y to algae/aquatic	:	mg/l Exposure time:	kirchneriella subcapitata (green algae)): 5.7 : 72 h) Test Guideline 201		
			mg/l Exposure time:	okirchneriella subcapitata (green algae)): 3.2 : 72 h) Test Guideline 201		
Toxicit	y to microorganisms	:	Exposure time: Test Type: Res	microorganism): > 1,000 mg/l : 3 h spiration inhibition) Test Guideline 209		
			Exposure time: Test Type: Res	l microorganism): < 100 mg/l : 3 h spiration inhibition 0 Test Guideline 209		
Toxicity)	y to fish (Chronic tox-	:	NOEC: 3.6 mg/l Exposure time: 31 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210			
	y to daphnia and other c invertebrates (Chron-	:	NOEC: 0.32 mg/l Exposure time: 21 d			





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ic tox	icity)		phnia magna (Water flea) CD Test Guideline 211
	istence and degrada	bility	
12.3 Bioa	ccumulative potentia	I	
<u>Com</u>	ponents:		
(+/-)- [,]	1,2,3,4,10,14b-Hexah	ydro-2-methylpyra	zino[2,1-a]pyrido[2,3-c][2]benzazepine:
	cumulation	: Species: On Bioconcentra	corhynchus mykiss (rainbow trout) ation factor (BCF): 334 CD Test Guideline 305
	ion coefficient: n- ol/water	: log Pow: 2.7	8
12.4 Mobi	lity in soil		
Com	ponents:		
(+/-)- [,]	1,2,3,4,10,14b-Hexah	ydro-2-methylpyra	zino[2,1-a]pyrido[2,3-c][2]benzazepine:
	bution among environ- al compartments	· : log Koc: 4.48	3
12.5 Resu	llts of PBT and vPvB	assessment	
Not re	elevant		
	r adverse effects ata available		
SECTION	13: Disposal con	siderations	
	e treatment methods		
Produ	uct	According to are not prod Waste codes	a accordance with local regulations. the European Waste Catalogue, Waste Codes uct specific, but application specific. s should be assigned by the user, preferably in vith the waste disposal authorities.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Contaminated packaging

Not regulated as a dangerous good

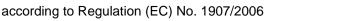
14.3 Transport hazard class(es)

Not regulated as a dangerous good

dling site for recycling or disposal.

: Empty containers should be taken to an approved waste han-

If not otherwise specified: Dispose of as unused product.





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14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks

: 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	:	Not applicable
the market and use of certain dangerous substances,		
preparations and articles (Annex XVII)		
REACH - Candidate List of Substances of Very High	:	Not applicable
Concern for Authorisation (Article 59).		
REACH - List of substances subject to authorisation	:	Not applicable
(Annex XIV)		
Regulation (EC) No 1005/2009 on substances that de-	:	Not applicable
plete the ozone layer		
Regulation (EU) 2019/1021 on persistent organic pollu-	•	Not applicable
tants (recast)		
Regulation (EC) No 649/2012 of the European Parlia-	:	Not applicable
ment and the Council concerning the export and import	-	
e , ,		
of dangerous chemicals		
Seveso III: Directive 2012/18/EU of the European Parlia	iment	t 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

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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

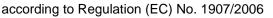
15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information

: Items where changes have been made to the previous version





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			are highlighted in lines.	the body of this document by two vertical		
Full te	ext of H-Statements					
H302		:	Harmful if swallow	ved.		
H361f	d	:	: Suspected of damaging fertility. Suspected of damaging			
11070			unborn child.			
H373		:	 May cause damage to organs through prolonged or repeate exposure if swallowed. 			
H411		:	Toxic to aquatic life with long lasting effects.			
Full te	ext of other abbreviat	ions				
Acute	Tox.	:	Acute toxicity			
Aquati	c Chronic	:	: Long-term (chronic) aquatic hazard			
Repr.		:	Reproductive toxicity			
STOT	RE	:	Specific target or	gan toxicity - repeated exposure		
GB EH	140	:	UK. EH40 WEL -	Workplace Exposure Limits		
GB EH	140 / TWA	:	: Long-term exposure limit (8-hour TWA reference period)			

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information



according to Regulation (EC) No. 1907/2006

Mirtazapine Solid Formulation

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	ces of key data used to ile the Safety Data t		al data, data from raw material SDSs, OECD search results and European Chemicals Agen- europa.eu/
Class	sification of the mixtu	re:	Classification procedure:
Repr	2	H361fd	Calculation method
STO	FRE 2	H373	Calculation method
Aqua	tic Chronic 3	H412	Calculation method

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