

Mirtazapine Disintegrating Formulation

Version 3.12 Revision Date: 01.10.2020 SDS Number: 50203-00016 Date of last issue: 23.03.2020
Date of first issue: 23.01.2015

Section 1: Identification

Product name : Mirtazapine Disintegrating Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33rd floor
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical


Section 2: Hazard identification**GHS Classification**

Acute toxicity (Oral) : Category 4

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Nervous system)

GHS label elements

Hazard pictograms : 

Signal word : Warning

Hazard statements : H302 Harmful if swallowed.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H373 May cause damage to organs (Nervous system) through prolonged or repeated exposure if swallowed.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P281 Use personal protective equipment as required.

Mirtazapine Disintegrating Formulation

Version 3.12 Revision Date: 01.10.2020 SDS Number: 50203-00016 Date of last issue: 23.03.2020
 Date of first issue: 23.01.2015

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

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

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 -< 30
Citric acid	77-92-9	< 10
Cellulose	9004-34-6	< 10
Magnesium stearate	557-04-0	< 10

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.

In case of skin contact : 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.
 Never give anything by mouth to an unconscious person.

Most important symptoms : Harmful if swallowed.

Mirtazapine Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.12	01.10.2020	50203-00016	Date of first issue: 23.01.2015

and effects, both acute and delayed		Suspected of damaging fertility. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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 products	:	Carbon oxides Nitrogen oxides (NO _x) Metal oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Sweep up or vacuum up spillage and collect in suitable container 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-

Mirtazapine Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.12	01.10.2020	50203-00016	Date of first issue: 23.01.2015

es, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	:	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. Wash skin thoroughly after handling. 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. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
Conditions for safe storage	:	Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents

Section 8: Exposure controls/personal protection**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / 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/m ³	Internal

Mirtazapine Disintegrating Formulation

Version 3.12 Revision Date: 01.10.2020 SDS Number: 50203-00016 Date of last issue: 23.03.2020
Date of first issue: 23.01.2015

		Wipe limit	250 µg/100 cm ²	Internal
Cellulose	9004-34-6	WES-TWA	10 mg/m ³	NZ OEL
		TWA	10 mg/m ³	ACGIH
Magnesium stearate	557-04-0	WES-TWA	10 mg/m ³	NZ OEL
		TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	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 designed 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

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type
Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance 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 end of workday.

Eye 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).

Section 9: Physical and chemical properties

Appearance : powder

Colour : No data available

Odour : No data available

Odour Threshold : No data available

SAFETY DATA SHEET



Mirtazapine Disintegrating Formulation



Version 3.12 Revision Date: 01.10.2020 SDS Number: 50203-00016 Date of last issue: 23.03.2020
Date of first issue: 23.01.2015

pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
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
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.

Mirtazapine Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.12	01.10.2020	50203-00016	Date of first issue: 23.01.2015

Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	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	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes	:	Inhalation Skin contact Ingestion Eye contact
-----------------	---	--

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 1,588 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	:	LD50 (Rat): 320 - 490 mg/kg
---------------------	---	-----------------------------

Citric acid:

Acute oral toxicity	:	LD50 (Mouse): 5,400 mg/kg
---------------------	---	---------------------------

Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity
-----------------------	---	---

Cellulose:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
---------------------	---	---------------------------

Acute inhalation toxicity	:	LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist
---------------------------	---	--

Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg
-----------------------	---	------------------------------

Magnesium stearate:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 423 Assessment: The substance or mixture has no acute oral toxicity Remarks: Based on data from similar materials
---------------------	---	--

Mirtazapine Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.12	01.10.2020	50203-00016	Date of first issue: 23.01.2015

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:**Citric acid:**

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Magnesium stearate:

Species : Rabbit
Result : No skin irritation
Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Citric acid:**

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

Magnesium stearate:

Species : Rabbit
Result : No eye irritation
Remarks : Based on data from similar materials

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Magnesium stearate:**

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

Mirtazapine Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.12	01.10.2020	50203-00016	Date of first issue: 23.01.2015

Chronic toxicity**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
Result: negative

Citric acid:

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

Test Type: in vitro micronucleus test
Result: positive

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

Cellulose:

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

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)

Mirtazapine Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.12	01.10.2020	50203-00016	Date of first issue: 23.01.2015

Species: Mouse
 Application Route: Ingestion
 Result: negative

Magnesium stearate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
 Result: negative
 Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
 Method: OECD Test Guideline 473
 Result: negative
 Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)
 Result: negative
 Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

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

Species : Mouse
 Application Route : Oral
 Exposure time : 18 month(s)
 LOAEL : 200 mg/kg body weight
 Result : equivocal
 Target Organs : Liver

Species : Rat
 Application Route : Oral
 Exposure time : 2 Years
 LOAEL : 20 mg/kg body weight
 Result : equivocal
 Target Organs : Liver, Thyroid

Cellulose:

Species : Rat
 Application Route : Ingestion
 Exposure time : 72 weeks
 Result : negative

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

Mirtazapine Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.12	01.10.2020	50203-00016	Date of first issue: 23.01.2015

Fertility: LOAEL: 15 mg/kg body weight
 Symptoms: Effect on estrous cycle, Increase of early resorptions
 Result: Animal testing did not show any effects on fertility., Embryotoxic effects and adverse effects on the offspring were detected.

Effects on foetal development : Test Type: Development
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: LOAEL: 100 mg/kg body weight
 Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects

Test Type: Development
 Species: Rabbit
 Application Route: Oral
 Developmental Toxicity: NOAEL: 40 mg/kg body weight
 Result: No adverse effects, No teratogenic effects

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

Citric acid:

Effects on foetal development : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Result: negative

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development
 Species: Rat
 Application Route: Ingestion
 Result: negative

Magnesium stearate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 422
 Result: negative
 Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
 Species: Rat

Mirtazapine Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.12	01.10.2020	50203-00016	Date of first issue: 23.01.2015

Application Route: Ingestion
 Result: negative
 Remarks: Based on data from similar materials

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Nervous system) through prolonged or repeated exposure if swallowed.

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 : Rat
 LOAEL : 120 mg/kg
 Application Route : Oral
 Exposure time : 13 Weeks
 Target Organs : Nervous system

Species : Dog
 LOAEL : 15 mg/kg
 Application Route : Oral
 Exposure time : 52 Weeks
 Target Organs : Nervous system
 Symptoms : Tremors

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

Citric acid:

Species : Rat
 NOAEL : 4,000 mg/kg
 LOAEL : 8,000 mg/kg
 Application Route : Ingestion
 Exposure time : 10 Days

Cellulose:

Species : Rat

Mirtazapine Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.12	01.10.2020	50203-00016	Date of first issue: 23.01.2015

NOAEL	:	>= 9,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

Magnesium stearate:

Species	:	Rat
NOAEL	:	> 100 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Remarks	:	Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:**

Ingestion	:	Symptoms: Drowsiness, constipation, dry mouth, asthenia, Dizziness, Disorientation
-----------	---	--

Section 12: Ecological information**Ecotoxicity****Components:****(+/-)-1,2,3,4,10,14b-Hexahydro-2-methylpyrazino[2,1-a]pyrido[2,3-c][2]benzazepine:**

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 6.92 mg/l Exposure time: 96 h Method: FDA 4.11
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 19.5 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 5.7 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 3.2 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 3.6 mg/l Exposure time: 31 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.32 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

Mirtazapine Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.12	01.10.2020	50203-00016	Date of first issue: 23.01.2015

Toxicity to microorganisms : EC50 (Natural microorganism): > 1,000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209

NOEC (Natural microorganism): < 100 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209

Citric acid:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
 Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,535 mg/l
 Exposure time: 24 h

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
 Exposure time: 48 h
 Remarks: Based on data from similar materials

Magnesium stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
 Exposure time: 48 h
 Method: DIN 38412
 Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 1 mg/l
 Exposure time: 47 h
 Test substance: Water Accommodated Fraction
 Method: Directive 67/548/EEC, Annex V, C.2.
 Remarks: Based on data from similar materials
 No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
 Exposure time: 72 h
 Test substance: Water Accommodated Fraction
 Method: OECD Test Guideline 201
 Remarks: Based on data from similar materials
 No toxicity at the limit of solubility

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
 Exposure time: 72 h
 Test substance: Water Accommodated Fraction
 Method: OECD Test Guideline 201
 Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l
 Exposure time: 16 h
 Test substance: Water Accommodated Fraction

Mirtazapine Disintegrating Formulation

Version 3.12 Revision Date: 01.10.2020 SDS Number: 50203-00016 Date of last issue: 23.03.2020
Date of first issue: 23.01.2015

Remarks: Based on data from similar materials

Persistence and degradability**Components:****Citric acid:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Cellulose:

Biodegradability : Result: Readily biodegradable.

Magnesium stearate:

Biodegradability : Result: Not biodegradable
Remarks: Based on data from similar materials

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

Bioaccumulation : Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 334
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 2.78

Citric acid:

Partition coefficient: n-octanol/water : log Pow: -1.72

Magnesium stearate:

Partition coefficient: n-octanol/water : log Pow: > 4

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

Distribution among environmental compartments : log Koc: 4.48

Other adverse effects

No data available

Section 13: Disposal considerations**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Mirtazapine Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.12	01.10.2020	50203-00016	Date of first issue: 23.01.2015

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.

National Regulations**NZS 5433**

Not regulated as a dangerous good

Section 15: Regulatory information**Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 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 Agency, <http://echa.europa.eu/>

Mirtazapine Disintegrating Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
3.12	01.10.2020	50203-00016	Date of first issue: 23.01.2015

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
NZ OEL	: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA	: 8-hour, time-weighted average
NZ OEL / WES-TWA	: Workplace Exposure Standard - Time Weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NZ / EN