

OTHER INFORMATION No additional information**3 COMPOSITION / INFORMATION ON INGREDIENTS**

General information: The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the composition table. Active ingredients in any concentration are listed.

Hazardous Component(s):

Chemical name	CAS-No.	Concentration
MIRTAZAPINE	85650-52-8	<=9.808%
Starch	9005-25-8	<=9.808%
Silicium dioxide	1343-98-2	<=1.471%
Salicylic Acid	69-72-7	<=1.462%
Titanium Dioxide	13463-67-7	<=0.617%
IRON OXIDE RED	1309-37-1	0.1%

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4 FIRST AID MEASURES

Inhalation: Move to fresh air. For breathing difficulties, oxygen may be necessary. If breathing stops, provide artificial respiration. Get medical attention.

Skin contact: Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing.

Eye contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if symptoms occur.

Ingestion: Do not induce vomiting. Get medical attention if symptoms occur.

Notes to the physician:

Hazards: See Sections 2 and 11. May cause nervous system effects.

Treatment: Treat supportively and symptomatically.

5 FIRE-FIGHTING MEASURES

Extinguishing media: Water spray, fog, CO₂, dry chemical, or alcohol resistant foam.

Unsuitable extinguishing media: None known.

Unusual Fire & Explosion Hazards: Emits toxic fumes under fire conditions.

Special Fire Fighting Procedures: Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6 ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Keep unnecessary personnel away.

Environmental precautions: Do not release into the environment.

Spill Cleanup Methods: Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Avoid dusty conditions and prevent wind dispersal. Collect in containers and seal securely. For waste disposal, see section 13 of the MSDS. Prevent runoff from entering drains, sewers, or streams.

7 HANDLING AND STORAGE

Handling: No specific hazard with intact tablets or capsules. In case of exposure to crushed or broken tablets/capsules, avoid contact with eyes and avoid prolonged or repeated contact with skin. Wash thoroughly after handling.

Storage: Keep container tightly closed in a cool, well-ventilated place. Protect from light. Protect from moisture.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION
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Exposure limits:

Chemical name	Type	Exposure Limit values	Source
Starch	TWA	10 mg/m ³	US. ACGIH Threshold Limit Values (2009)
Starch - Respirable fraction.	PEL	5 mg/m ³	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Starch - Total dust.	PEL	15 mg/m ³	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
Titanium Dioxide	TWA	10 mg/m ³	US. ACGIH Threshold Limit Values (2009)
Titanium Dioxide - Total dust.	PEL	15 mg/m ³	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
IRON OXIDE RED - Fume.	PEL	10 mg/m ³	US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (02 2006)
IRON OXIDE RED - Respirable fraction.	TWA	5 mg/m ³	US. ACGIH Threshold Limit Values (01 2010)
MIRTAZAPINE	TWA	25 µg/m ³ (OEB 3)	Merck
	Wipe Limit	250 µg/100 cm ²	Merck

OEB (Occupational Exposure Band) is an internal Merck control band.

Protective Measures: No special containment required with normal handling of finished product. Use local exhaust ventilation to control residual dust from broken or crushed tablets when handling in bulk quantities.

Respiratory Protection: No specific recommendation made, but respiratory protection must be used if the general level exceeds the Recommended Occupational Exposure Limit

Hand protection: Disposable chemical resistant gloves wherever the potential exists for direct exposure to residual dust from crushed or broken tablets or capsules.

Eye protection: If contact is likely, safety glasses with side shields are recommended.

Skin and Body Protection: Work uniform or laboratory coat when there is potential for direct contact with the residual dust from crushed or broken tablets.

Hygiene measures: Wash skin thoroughly with soap and water.

9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance:

Physical State: Solid
Form: Tablets

10 STABILITY AND REACTIVITY

Stability: Stable

Possibility of hazardous reactions: Stable

Conditions to avoid: Moisture. Excessive heat.

Incompatible materials: None under normal conditions.

Hazardous decomposition products: Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors.

11 TOXICOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations. Indicated for the treatment of depression.

Specified substance(s):
Acute Toxicity (Oral);
Name

MIRTAZAPINE

Starch

Salicylic Acid

Titanium Dioxide

Test results

LD50 (Rat, Female): 320 mg/kg

LD50 (Rat, Male): 490 mg/kg

No data available.

LD50 (Mouse): 480 mg/kg

LD50 (Rat): 891 mg/kg Harmful if swallowed.

No data available.

Acute Toxicity (Dermal):
Name

MIRTAZAPINE

Starch

Salicylic Acid

Titanium Dioxide

Test results

No data available.

No data available.

LD50 (Rat): > 2 g/kg

No data available.

Acute Toxicity (Inhalation):
Name

MIRTAZAPINE

Starch

Salicylic Acid

Titanium Dioxide

Test results

No data available.

No data available.

LC50 (Rat, 1 h): > 0.9 mg/l

No data available.

Repeated dose toxicity:
Name

MIRTAZAPINE

Starch

Titanium Dioxide

Test results

Mirtazapine did not induce systemic effects in rats or dogs in 13-week or 52-week studies.

No data available.

No data available.

Inhalation:

No data available.

Ingestion:

No data available.

Skin corrosion/irritation:

No data available.

Serious eye damage/eye irritation:

No data available.

Respiratory sensitizer/Skin sensitizer:

No data available.

Carcinogenicity:

No data available.

The following components have been identified as having carcinogenic properties

Name	CAS-No.	Concentration
Titanium Dioxide	13463-67-7	<=0.617%

Mutagenesis:

Negative in a battery of in vitro genotoxicity assays. (Based on individual component data.)

Reproductive toxicity:

No adverse developmental effects were observed. No effect on fertility was observed in animals. (Based on individual component data.)

Other Effects: No additional information

12 ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

Ecotoxicity:

Product:

Chronic Toxicity(Fish): No data available.

Specified substance(s):

Acute toxicity(Fish):

Name

MIRTAZAPINE
Starch
Salicylic Acid
Titanium Dioxide

Test results

LC50 (Fathead minnow (*Pimephales promelas*), 96 h): 6.92 mg/l
No data available.
LC50 (Ide, silver or golden orfe (*Leuciscus idus*), 48 h): 90 mg/l
LC50 (Mummichog (*Fundulus heteroclitus*), 96 h): > 1,000 mg/l Mortality
LC50 (Mummichog (*Fundulus heteroclitus*), 72 h): > 1,000 mg/l Mortality
LC50 (Mummichog (*Fundulus heteroclitus*), 48 h): > 1,000 mg/l Mortality
LC50 (Mummichog (*Fundulus heteroclitus*), 24 h): > 1,000 mg/l Mortality

Acute toxicity(Aquatic invertebrates):

Name

MIRTAZAPINE
Starch
Salicylic Acid
Titanium Dioxide

Test results

EC 50 (Water flea (*Daphnia*), 48 h): 19.5 - 25.8 mg/l
No data available.
EC 50 (Water flea (*Daphnia magna*), 24 h): 105 mg/l
EC 50 (Water flea (*Daphnia magna*), 48 h): > 1,000 mg/l Intoxication

Chronic Toxicity(Aquatic invertebrates):

Name

MIRTAZAPINE
Starch
Titanium Dioxide

Test results

EC 50 (Earthworm, 14 d): > 1,000 mg/l
No data available.
No data available.

Acute toxicity(Aquatic plants):

Name

MIRTAZAPINE
Starch
Salicylic Acid
Titanium Dioxide

Test results

No data available.
No data available.
NOEC (Duckweed (*Lemna minor*), 7 d): 30 mg/l
No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: Not expected to bioaccumulate.

Mobility: Immobile in soil.

13 DISPOSAL CONSIDERATIONS

Disposal Methods: Do not allow runoff to sewer, waterway or ground. Discharge, treatment, or disposal may be subject to national, state, or local laws.

Measures for Avoidance and Incineration is the most effective method of disposal in most instances. Do not

Recovery: allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14 TRANSPORT INFORMATION

DOT

Not regulated.

IMDG - International Maritime Dangerous Goods Code

Not regulated.

IATA - International Air Transport Association

Not regulated.

15 REGULATORY INFORMATION

US Regulations

- **CERCLA Hazardous Substance List (40 CFR 302.4):**

None

- **Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):**

None

- **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):**

None

SARA Title III

- **Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):**

None

- **Section 313 Toxic Release Inventory (40 CFR 372):**

None present or none present in regulated quantities.

State Regulations

- **California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):**

No ingredient regulated by CA Prop 65 present.

- **Massachusetts Right-To-Know List:**

Starch	Listed
Silicium dioxide	Listed
Titanium Dioxide	Listed
IRON OXIDE RED	Listed

- **New Jersey Right-To-Know List:**

Silicium dioxide	Listed
Titanium Dioxide	Listed

- **Pennsylvania Right-To-Know List:**

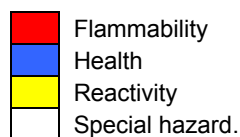
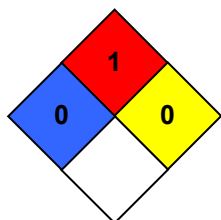
Starch	Listed
Silicium dioxide	Listed

16 OTHER INFORMATION

OTHER INFORMATION

This SDS is written to provide health and safety information

for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

NFPA Hazard ID

Hazard rating: 0 - Minimal; 1 - Slight; 2 - Moderate; 3 - Serious; 4 - Severe

Revision Information:

Not relevant.

Issue Date:

25.07.2013

Disclaimer:

This information is provided without warranty. The information is believed to be correct. This information should be used to make an independent determination of the methods to safeguard workers and the environment.