

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 1 of 12
	SAFETY DATA SHEET (SDS)	
Product Name	Sildenafil for Oral Suspension, 10 mg/mL	

1. Product Information

Product Name: **Sildenafil for Oral Suspension.**

2. Composition/Information on Ingredients

Hazardous

Ingredient	CAS number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Citric acid	77-92-9	201-069-1	Xi; R36	Eye Irrit. 2(H319)	<3.0
Colloidal silicon dioxide	7631-86-9	231-545-4	Not listed	Not listed	*
Sildenafil citrate	171599-83-0	Not Listed	Xn; R22	Acute Tox. 4(H302) Eye Irrit. 2B(H320) Aquatic Acute 3 (H402) Aquatic Chronic 3 (H412)	3.5
Titanium dioxide	13463-67-7	236-675-5	Not listed	Not listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Flavor	NOT ASSIGNED	Not listed	Not listed	Not listed	*
Sodium benzoate	532-32-1	208-534-8	Not listed	Not listed	*
Sodium citrate	68-04-2	200-675-3	Not listed	Not listed	*
Sorbitol	6706-59-8	Not listed	Not listed	Not listed	*
Sucralose	56038-13-2	259-952-2	Not listed	Not listed	*
Xanthan gum	11138-66-2	234-394-2	Not listed	Not listed	*

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 2 of 12
	SAFETY DATA SHEET (SDS)	
Product Name	Sildenafil for Oral Suspension, 10 mg/mL	

3. Hazards Identification

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

EU Classification:

EU Indication of danger: Not classified

Label Elements

Hazard Statements: May form combustible dust concentrations in air

Other Hazards No data available

Australian Hazard Classification (NOHSC) Non-Hazardous Substance. Non-Dangerous Goods.

4. First Aid Measures

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of

Exposure: For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - toxicological Information.

Medical Conditions None known

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 3 of 12
	SAFETY DATA SHEET (SDS)	
Product Name	Sildenafil for Oral Suspension, 10 mg/mL	

**Aggravated by
Exposure:**

Indication of the Immediate Medical Attention and Special Treatment Needed

5. Fire Fighting Measures

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion

Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning /

Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for

Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 4 of 12
	SAFETY DATA SHEET (SDS)	
Product Name	Sildenafil for Oral Suspension, 10 mg/mL	

7. Handling and Storage

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. Exposure Controls/Personal Protection

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Colloidal silicon dioxide

Australia TWA	2 mg/m ³
Austria OEL – MAKs	4 mg/m ³ ; 0.3 mg/m ³
Czech Republic OEL - TWA	0.1 mg/m ³ ; 4.0 mg/m ³
Estonia OEL – TWA	2 mg/m ³
Finland OEL – TWA	5 mg/m ³
Germany - TRGS 900 – TWAs	4 mg/m ³
Germany (DFG) – MAK	4 mg/m ³
Ireland OEL – TWAs	6 mg/m ³ ; 2.4 mg/m ³
Latvia OEL – TWA	1 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf Listed
Slovakia OEL – TWA	4.0 mg/m ³
Switzerland OEL -TWAs	4 mg/m ³ ; 0.3 mg/m ³

Sildenafil citrate

OEL TWA-8 Hr:	350µg/m ³
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Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	10 mg/m ³
Austria OEL – MAKs	5 mg/m ³

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 5 of 12
	SAFETY DATA SHEET (SDS)	
Product Name	Sildenafil for Oral Suspension, 10 mg/mL	

Belgium OEL – TWA	10 mg/m ³
Bulgaria OEL – TWA	10.0 mg/m ³
Denmark OEL – TWA	6 mg/m ³
Estonia OEL – TWA	5 mg/m ³
France OEL – TWA	10 mg/m ³
Greece OEL – TWA	10 mg/m ³
	5 mg/m ³
Ireland OEL – TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL – TWA	10 mg/m ³
Lithuania OEL – TWA	5 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL – TWA	10.0 mg/m ³
Portugal OEL – TWA	10 mg/m ³
Romania OEL – TWA	10 mg/m ³
Russia OEL – TWA	10 mg/m ³
Spain OEL – TWA	10 mg/m ³
Sweden OEL – TWAs	5 mg/m ³
Switzerland OEL – TWAs	3 mg/m ³
Vietnam OEL – TWAs	6 mg/m ³ ; 5 mg/m ³

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal protective Equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes

Wear safety glasses or goggles if eye contact is possible.

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 6 of 12
	SAFETY DATA SHEET (SDS)	
Product Name	Sildenafil for Oral Suspension, 10 mg/mL	

9. Physical and Chemical Properties

Physical State:	Powder
Odor:	No data available
Molecular Formula:	Mixture
Solvent Solubility	No data available
Water Solubility:	No data available
pH:	No data available
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available
Partition Coefficient: (Method, pH, Endpoint, Value)	
Sucralose	No data available
Sorbitol	No data available
Titanium dioxide	No data available
Sodium benzoate	No data available
Xanthan gum	No data available
Colloidal silicon dioxide	No data available
Flavor	No data available
Sodium Citrate	No data available
Sildenafil citrate	Predicted 7.4 Log D 2.26
Citric acid	No data available
Decomposition Temperature (°C):	No data available
Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available
Flammability:	
Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 7 of 12
	SAFETY DATA SHEET (SDS)	
Product Name	Sildenafil for Oral Suspension, 10 mg/mL	

10. Stability and Reactivity

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	None known
Incompatible Materials:	As a precautionary measure, keep away
from strong oxidizers	
Hazardous Decomposition	
Products:	No data available

11. Toxicological Information

Information on Toxicological Effects

General Information:

The information included in this section describes the potential hazards of the individual Ingredients

Short Term:

May be harmful if swallowed. May cause eye irritation (based on components)

Long Term:

Animal studies indicate that this material may cause adverse effects on the cardiovascular system.

Known Clinical Effects:

Adverse effects most commonly reported in clinical use include difficult digestion (dyspepsia), nose bleed, headache, flushing, insomnia, abnormal redness of skin (erythema), difficulty breathing, muscle pain, fever, gastrointestinal irritation, tingling/itching (paresthesia), transient changes in light perception and color vision, effects on hearing, and effects on vision.

Acute Toxicity: (Species, Route, End Point, Dose)

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg

Rat Subcutaneous LD50 50 mg/kg

Sodium benzoate

Rat Oral LD50 4,070 mg/kg

Mouse Oral LD50 1600mg/kg

Xanthan gum

Rat Oral LD50 > 5000 mg/kg

Sildenafil citrate

Rat Oral LDmin. 300-500 mg/kg

Mouse Oral LDmin. 500-1000 mg/kg

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 8 of 12
	SAFETY DATA SHEET (SDS)	
Product Name	Sildenafil for Oral Suspension, 10 mg/mL	

Rat Dermal LD50 > 2000 mg/kg

Citric acid

Rat Oral LD50 3000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Sildenafil citrate

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Non-irritating

Skin Sensitization Guinea Pig Negative

Citric acid

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Sodium benzoate

10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood

10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

Sildenafil citrate

6 Month(s) Rat Oral 3 mg/kg/day NOAEL Adrenal gland, Liver, Thyroid

6 Month(s) Dog Oral 15 mg/kg/day NOAEL Cardiovascular system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Sodium benzoate

Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity

Sildenafil citrate

Reproductive & Fertility Rat Oral 60 mg/kg/day NOEL No effects at maximum dose

Embryo / Fetal Development Rat Oral 50 mg/kg/day NOEL Maternal Toxicity, Not Teratogenic

Embryo / Fetal Development Rabbit Oral 50 mg/kg/day NOEL Maternal Toxicity, Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Sildenafil citrate

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vitro Cytogenetics Human Lymphocytes Negative

In Vivo Micronucleus Chromosome Aberration Mouse Bone Marrow Negative

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 9 of 12
	SAFETY DATA SHEET (SDS)	
Product Name	Sildenafil for Oral Suspension, 10 mg/mL	

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Sildenafil citrate

24 Month(s) Mouse Oral 5 mg/kg/day NOAEL Not carcinogenic

24 Month(s) Rat Oral 60 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

Colloidal silicon dioxide

IARC: Group 3 (Not Classifiable)

12. Ecological Information

Environmental Overview: In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater. Harmful effects to aquatic organisms could occur.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Sildenafil citrate

Daphnia magna (Water Flea) TAD EC50 48 Hours 14 mg/L

Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours > 9.5 mg/L

Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 20 mg/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e.LC/EC50) is not achievable

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Sildenafil citrate

Activated sludge OECD EC50 > 1000 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Sildenafil citrate

Predicted 7.4 Log D 2.26

Mobility in Soil: No data available

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 10 of 12
	SAFETY DATA SHEET (SDS)	
Product Name	Sildenafil for Oral Suspension, 10 mg/mL	

13. Disposal Considerations

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. Transport Information

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Citric acid

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

Colloidal silicon dioxide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 11 of 12
	SAFETY DATA SHEET (SDS)	
Product Name	Sildenafil for Oral Suspension, 10 mg/mL	

Flavor

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Sildenafil citrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Sodium benzoate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-675-3

Sorbitol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Sucralose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	259-952-2

Titanium dioxide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

Xanthan gum

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	234-394-2

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 12 of 12
	SAFETY DATA SHEET (SDS)	
Product Name	Sildenafil for Oral Suspension, 10 mg/mL	

16. Other Information

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
 Serious eye damage/eye irritation-Cat. 2B; H320 - Causes eye irritation
 Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life
 Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects
 Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

Xn - Harmful
 Xi – Irritant

R22 - Harmful if swallowed.
 R36 – Irritating to eyes

Prepared by: **MSN Pharmaceutical Inc, Piscataway, New Jersey – 08554**

MSN Pharmaceutical Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

Disclaimer: This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. It is not meant to be an all-inclusive document on worldwide hazard communications regulations. This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate mechanisms to prevent employee exposures, property damage or release to the environment.

End Of Safety Data Sheet