



# SAFETY DATA SHEET

Revision Date 29-Sep-2018

Version 2

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### Product identifier

**Product Name** Rapaflo

### Other means of identification

**Product Code** FG00110

**Synonyms** Silodosin

### Recommended use of the chemical and restrictions on use

**Recommended Use** BPH

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

### Details of the supplier of the safety data sheet

#### **Manufacturer**

Allergan plc  
5 Giralda Farms  
Madison, NJ USA 07940  
+1-800-272-5525

**E-mail address** SDS@Allergan.com

### Emergency telephone number

**Emergency Telephone** Call CHEMTREC Day or Night  
Within USA or Canada: 1-800-424-9300  
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

## 2. HAZARDS IDENTIFICATION

### Classification

#### **OSHA Regulatory Status**

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity - Oral	Category 4
Acute toxicity - Dermal	Category 3
Acute toxicity - Inhalation (Dusts/Mists)	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2
Carcinogenicity	Category 2
Reproductive toxicity	Category 2

### Label elements

#### Emergency Overview

#### **Danger**

#### **Hazard statements**

H311 - Toxic in contact with skin  
H315 - Causes skin irritation  
H319 - Causes serious eye irritation  
H351 - Suspected of causing cancer

H361 - Suspected of damaging fertility or the unborn child



**Appearance** No information available

**Physical state** No information available

**Odor** No information available

**Chemical Name**

**Sildenafil**

**Symptoms**

Orthostatic hypertension, syncope, toxic skin eruption, purpura, skin rash, pruritus, urticarial, diarrhea, jaundice, impaired hepatic function, elevated hepatic enzyme levels, allergic type reactions, dizziness, headache, retrograde ejaculation, nasal congestion, nasopharyngitis

**Chemical Name**

**Sildenafil**

**Medical Conditions Aggravated by Exposure**

Patients with severe renal or hepatic impairment [Creatinine Clearance (CCr < 30 mL/min)]. ((Child-Pugh score > 10). Concomitant administration with strong Cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ketoconazole, clarithromycin, itraconazole, ritonavir). Patients with a history of hypersensitivity to sildenafil or any of the ingredients of RAPAFLU.

**Precautionary statements**

P270 - Do not eat, drink or smoke when using this product

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

P330 - Rinse mouth

P361 - Remove/Take off immediately all contaminated clothing

P363 - Wash contaminated clothing before reuse

P322 - Specific measures (see supplemental first aid instructions on this label)

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray

P271 - Use only outdoors or in a well-ventilated area

P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P312 - Call a POISON CENTER or doctor if you feel unwell

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P321 - Specific treatment (see supplemental first aid instructions on this label)

P332 + P313 - If skin irritation occurs: Get medical advice/attention

P362 - Take off contaminated clothing and wash before reuse

P264 - Wash face, hands and any exposed skin thoroughly after handling

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P337 + P313 - If eye irritation persists: Get medical advice/attention

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P281 - Use personal protective equipment as required

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P405 - Store locked up

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

P280 - Wear protective gloves/protective clothing/eye protection/face protection

**Other Information**

Unknown Acute Toxicity

81% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	EINECS	Weight-%
SODIUM LAURYL SULFATE NF	151-21-3	205-788-1	10 - 30*
Silodosin	160970-54-7	N/A	7 - 13*
MANNITOL USP	69-65-8	200-711-8	3 - 7*
Tropium Chloride	10405-02-4	233-875-4	0.1 - 1*
Titanium Dioxide	1317-70-0	215-280-1	0.1 - 1*
MICROCRYSTALLINE CELLULOSE(AVICEL PH102)	9004-34-6	232-674-9	0.1 - 1*
LACTOSE MONOHYDRATE NF(FAST FLOW)(SPRAY DRIED)	64044-51-5	N/A	0.1 - 1*
POVIDONE USP(PLASDONE K-29-32)	9003-39-8	N/A	<0.1*
MAGNESIUM STEARATE NF(VEGETABLE SOURCE)	557-04-0	209-150-3	<0.1*
TALC USP(1656)	14807-96-6	238-877-9	<0.1*
Sucrose Palmitate	26446-38-8	247-706-7	<0.1*
STEARIC ACID NF	57-11-4	200-313-4	<0.1*
PWDRD CELLULOSE BW40 NF	9004-32-4	N/A	<0.1*
FERRIC OXIDE NF (RED 30)	1309-37-1	215-168-2	<0.1*
CROSCARMELLOSE SODIUM NF(TYPE A, AC-DI-SOL)	74811-65-7	N/A	<0.1*
COLOIDAL SILICON DIOXIDE(CAB-O-SIL GRADE M-5P)	112945-52-5	N/A	<0.1*
POLYETHYLENE GLYCOL NF6000	25833-68-3	N/A	<0.1*
CORN STARCH NF	9005-25-8	232-679-6	<0.1*
White Cresin Wax	8002-74-2	232-315-6	<0.1*
CARNABUA WAX NF	8015-86-9	232-399-4	<0.1*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

### 4. FIRST AID MEASURES

#### First aid measures

<b>Eye contact</b>	Rinse immediately with plenty of water and seek medical advice.
<b>Skin Contact</b>	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
<b>Inhalation</b>	Remove to fresh air.
<b>Ingestion</b>	Consult a physician if necessary.

#### Chemical Name

Silodosin

#### Note to physicians

RAPAFLO was evaluated at doses of up to 48 mg/day in healthy male subjects. The dose-limiting adverse event was postural hypotension. Should overdose of RAPAFLO lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by maintaining the patient in the supine position. If this measure is inadequate, administration of intravenous fluid should be considered. If necessary, vasopressors could be used, and renal function should be monitored and supported as needed. Dialysis is unlikely to be of significant benefit since silodosin is highly (97%) protein bound.

### 5. FIRE-FIGHTING MEASURES

#### Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable extinguishing media**

None known.

**Specific hazards arising from the chemical**

Fire may produce irritating, corrosive and/or toxic gases.

**Explosion data**

**Sensitivity to Mechanical Impact**

Not impact sensitive.

**Sensitivity to Static Discharge**

Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

**Protective equipment and precautions for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

**6. ACCIDENTAL RELEASE MEASURES**

**Personal precautions**

Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

**Environmental precautions**

Do not allow into any sewer, on the ground or into any body of water.

**Methods for containment**

Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up**

Avoid creating dust.

**7. HANDLING AND STORAGE**

**Advice on safe handling**

Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.

**Storage Conditions**

Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

**Incompatible materials**

None known based on information supplied.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Control parameters**

**Exposure Guidelines**

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL (ug/m <sup>3</sup> )
Silodosin 160970-54-7	N/A	N/A	N/A	10
Trospium Chloride 10405-02-4	N/A	N/A	N/A	100 ug/m <sup>3</sup>
MICROCRYSTALLINE CELLULOSE(AVICEL PH102) 9004-34-6	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 5 mg/m <sup>3</sup> (vacated) STEL: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust TWA: 1 mg/m <sup>3</sup>	N/A
MAGNESIUM STEARATE NF(VEGETABLE SOURCE) 557-04-0	TWA: 10 mg/m <sup>3</sup> inhalable particulate matter TWA: 3 mg/m <sup>3</sup> respirable particulate matter TWA: 10 mg/m <sup>3</sup> inhalable particulate matter except stearates of toxic metals TWA: 3 mg/m <sup>3</sup> respirable	N/A	N/A	N/A

	particulate matter except stearates of toxic metals			
TALC USP(1656) 14807-96-6	TWA: 2 mg/m <sup>3</sup> particulate matter containing no asbestos and <1% crystalline silica, respirable particulate matter	(vacated) TWA: 2 mg/m <sup>3</sup> respirable dust <1% Crystalline silica, containing no Asbestos TWA: 20 mppcf if 1% Quartz or more;use Quartz limit	IDLH: 1000 mg/m <sup>3</sup> TWA: 2 mg/m <sup>3</sup> containing no Asbestos and <1% Quartz respirable dust	N/A
STEARIC ACID NF 57-11-4	TWA: 10 mg/m <sup>3</sup> inhalable particulate matter TWA: 3 mg/m <sup>3</sup> respirable particulate matter	N/A	N/A	N/A
FERRIC OXIDE NF (RED 30) 1309-37-1	TWA: 5 mg/m <sup>3</sup> respirable particulate matter	TWA: 10 mg/m <sup>3</sup> fume TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 10 mg/m <sup>3</sup> fume and total dust Iron oxide (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction regulated under Rouge	IDLH: 2500 mg/m <sup>3</sup> Fe dust and fume TWA: 5 mg/m <sup>3</sup> Fe dust and fume	N/A
CORN STARCH NF 9005-25-8	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust	N/A
White Cresin Wax 8002-74-2	TWA: 2 mg/m <sup>3</sup> fume	(vacated) TWA: 2 mg/m <sup>3</sup>	TWA: 2 mg/m <sup>3</sup> fume	N/A

**Appropriate engineering controls**

**Engineering Controls**

The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**

No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

**Skin and body protection**

During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

**Respiratory protection**

Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Information on basic physical and chemical properties**

<b>Physical state</b>	No information available	<b>Appearance</b>	No information available
<b>Color</b>	No information available	<b>Odor</b>	No information available
<b>Odor threshold</b>	No information available		



			upper airway swelling may be life threatening. May cause irritation to skin. Prolonged or repeated skin contact may cause dermatitis (dry, red skin).	water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.
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Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
SODIUM LAURYL SULFATE NF	= 1288 mg/kg ( Rat )	= 200 mg/kg ( Rabbit )	> 3900 mg/m <sup>3</sup> ( Rat ) 1 h
MANNITOL USP	= 13500 mg/kg ( Rat )	N/A	N/A
Tropium Chloride	= 1510 mg/kg ( Rat )	N/A	N/A
MICROCRYSTALLINE CELLULOSE(AVICEL PH102)	> 5 g/kg ( Rat )	> 2 g/kg ( Rabbit )	> 5800 mg/m <sup>3</sup> ( Rat ) 4 h
POVIDONE USP(PLASDONE K-29-32)	= 100 g/kg ( Rat )	N/A	N/A
STEARIC ACID NF	= 4600 mg/kg ( Rat )	> 5 g/kg ( Rabbit )	N/A
PWDRD CELLULOSE BW40 NF	= 27000 mg/kg ( Rat )	> 2 g/kg ( Rabbit )	> 5800 mg/m <sup>3</sup> ( Rat ) 4 h
FERRIC OXIDE NF (RED 30)	> 10000 mg/kg ( Rat )	N/A	N/A
COLOIDAL SILICON DIOXIDE(CAB-O-SIL GRADE M-5P)	= 3160 mg/kg ( Rat )	N/A	N/A
White Cresin Wax	> 5000 mg/kg ( Rat )	> 3600 mg/kg ( Rabbit )	N/A

#### Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Silodosin	Genotoxic in vitro at high concentrations, not genotoxic in vivo.	Carcinogenic in mice and rats but relevance to human health is unclear.	Not teratogenic in rats or rabbits. Studies in female rats did not show fertility impairment, however male rats did show significant sperm count and viability reductions.	No information available
Tropium Chloride	Not mutagenic in the standard battery of tests.	Animal studies in mice and rats have not shown carcinogenicity.	Studies in rats and rabbits have not shown statistically significant levels of teratogenicity or harm to the fetus.	Detectable amounts of this compound have been identified in the milk of nursing women receiving this drug. Caution should be exercised when taking this compound is administered to nursing women.
POVIDONE USP(PLASDONE K-29-32)	No information available.	Not suspected of being a human carcinogen.	No information available.	No information available

Target Organ Effects Prostate.

#### Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 81% of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral) 1690 mg/kg

ATEmix (dermal) 787 mg/kg

ATEmix (inhalation-dust/mist) 1.3 mg/l

## 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

Toxic to aquatic life with long lasting effects

86% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
SODIUM LAURYL SULFATE NF 151-21-3	53: 72 h <i>Desmodesmus subspicatus</i> mg/L EC50 30 - 100: 96 h <i>Desmodesmus subspicatus</i> mg/L EC50 117: 96 h <i>Pseudokirchneriella subcapitata</i> mg/L EC50 3.59 - 15.6: 96 h <i>Pseudokirchneriella subcapitata</i> mg/L EC50 static	4.06 - 5.75: 96 h <i>Lepomis macrochirus</i> mg/L LC50 static 10.8 - 16.6: 96 h <i>Poecilia reticulata</i> mg/L LC50 static 4.3 - 8.5: 96 h <i>Oncorhynchus mykiss</i> mg/L LC50 static 22.1 - 22.8: 96 h <i>Pimephales promelas</i> mg/L LC50 static 4.2 - 4.8: 96 h <i>Lepomis macrochirus</i> mg/L LC50 flow-through 4.5: 96 h <i>Lepomis macrochirus</i> mg/L LC50 13.5 - 18.3: 96 h <i>Poecilia reticulata</i> mg/L LC50 semi-static 7.97: 96 h <i>Brachydanio rerio</i> mg/L LC50 flow-through 6.2 - 9.6: 96 h <i>Pimephales promelas</i> mg/L LC50 1.31: 96 h <i>Cyprinus carpio</i> mg/L LC50 semi-static 4.62: 96 h <i>Oncorhynchus mykiss</i> mg/L LC50 flow-through 8 - 12.5: 96 h <i>Pimephales promelas</i> mg/L LC50 static 4.2: 96 h <i>Oncorhynchus mykiss</i> mg/L LC50 9.9 - 20.1: 96 h <i>Brachydanio rerio</i> mg/L LC50 semi-static 10.2 - 22.5: 96 h <i>Pimephales promelas</i> mg/L LC50 semi-static 15 - 18.9: 96 h <i>Pimephales promelas</i> mg/L LC50 static 5.8 - 7.5: 96 h <i>Pimephales promelas</i> mg/L LC50 static	1.8: 48 h <i>Daphnia magna</i> mg/L EC50
TALC USP(1656) 14807-96-6	N/A	100: 96 h <i>Brachydanio rerio</i> g/L LC50 semi-static	N/A

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
SODIUM LAURYL SULFATE NF 151-21-3	N/A	N/A	N/A	1.6
Tropium Chloride 10405-02-4	No information available	No information available	No information available	Log P = 0.70

**Other adverse effects** No information available

**13. DISPOSAL CONSIDERATIONS**

**Waste treatment methods**

**Disposal of wastes** Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging** Do not reuse container. Dispose of contents/containers in accordance with local regulations.

**14. TRANSPORT INFORMATION**

**DOT** Not regulated

**TDG** Not regulated

**ICAO (air)** Not regulated



<b>IATA</b>	Not regulated
<b>IMDG</b>	Not regulated
<b>ADR</b>	Not regulated
<b>ADN</b>	Not regulated

## 15. REGULATORY INFORMATION

### International Inventories

<b>TSCA</b>	Not Listed
<b>DSL/NDSL</b>	Not Listed
<b>EINECS/ELINCS</b>	Not Listed

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

### US Federal Regulations

Chemical Name	ACGIH	IARC	NTP	OSHA
MICROCRYSTALLINE CELLULO(AVICEL PH102) 9004-34-6	-	Group 1	Known	X
POVIDONE USP(PLASDONE K-29-32) 9003-39-8	-	Group 3	-	-
TALC USP(1656) 14807-96-6	-	Group 3	-	X
FERRIC OXIDE NF (RED 30) 1309-37-1	-	Group 3	-	-
COLOIDAL SILICON DIOXIDE(CAB-O-SIL GRADE M-5P) 112945-52-5	-	Group 3	-	-

### SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

### SARA 311/312 Hazard Categories

<b>Acute health hazard</b>	No
<b>Chronic Health Hazard</b>	No
<b>Fire hazard</b>	No
<b>Sudden release of pressure hazard</b>	No
<b>Reactive Hazard</b>	No

### CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

### CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

### US State Regulations

#### California Proposition 65

This product does not contain any Proposition 65 chemicals

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Chemical Name	California Proposition 65
MICROCRYSTALLINE CELLULOSE(AVICEL PH102) - 9004-34-6	Carcinogen

**U.S. State Right-to-Know Regulations****16. OTHER INFORMATION**

Revision Date 29-Sep-2018  
Revision Note No information available

**Disclaimer**

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**