SAFETY DATA SHEET

Revision Date 02-Oct-2018 **Version** 10

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

Product identifier
Product Name Namzaric

Other means of identification
Product Code FG00077
Synonyms None

Recommended use of the chemical and restrictions on use
Recommended Use Alzheimer's

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 3
Acute toxicity - Inhalation (Dusts/Mists)	Category 4

Label elements

Emergency Overview

Danger

Hazard statements
H301 - Toxic if swallowed
H332 - Harmful if inhaled

Appearance Capsule **Physical state** Solid **Odor** No information available

Chemical Name	Symptoms
Donepezil HCL	The most common symptoms seen in therapeutic use include: nausea, diarrhea, insomnia, vomiting, muscle cramp, fatigue and anorexia.
Memantine Hydrochloride	Most common are dizziness, headache, confusion and constipation

Chemical Name	Medical Conditions Aggravated by Exposure
Donepezil HCL	When administered for therapeutic use, pre-existing asthma,ulcers, cardiac abnormalities, hepatic, bladder and neurological conditions may be aggravated by exposure
Memantine Hydrochloride	Contraindication include hypersensitivity to any component of this product hepatic impairment

Precautionary statements
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P321 - Specific treatment (see supplemental first aid instructions on this label)
P330 - Rinse mouth
P405 - Store locked up
P501 - Dispose of contents/ container to an approved waste disposal plant
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

Other Information
Unknown Acute Toxicity 29% 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-%
LACTOSE MONOHYDRATE NF(FAST FLOW)(SPRAY DRIED)	64044-51-5	N/A	10 - 30*
Colloidal Silica Anhydrous	7631-86-9	231-545-4	10 - 30*
Medium Chain Triglycerides	73398-61-5	277-452-2	7 - 13*
HydroxypropylMethlcellulose K100 Prem	9004-65-3	N/A	7 - 13*
ETHYLCELLULOSE NF ETHOCEL 100	9004-57-3	N/A	7 - 13*
Donepezil HCL	120011-70-3	N/A	7 - 13*
CONFECTIONERS SUGAR 6XWITH CORN STARCH	57-50-1	200-334-9	5 - 10*
Memantine Hydrochloride	41100-52-1	255-219-6	3 - 7*
CORN STARCH NF	9005-25-8	232-679-6	3 - 7*
UREA USP	57-13-6	200-315-5	3 - 7*

Tetracycline	60-54-8	200-481-9	3 - 7*
Sodium salicylate	54-21-7	200-198-0	3 - 7*
Pirenoxine	1043-21-6	213-872-4	3 - 7*
Asenapine	85650-56-2	288-064-8	3 - 7*
Abicipar	1327278-94-3	N/A	3 - 7*
POLYETHYLENE GLYCOL NF6000	25833-68-3	N/A	1 - 5*
TALC USP(1656)	14807-96-6	238-877-9	1 - 5*
Oleic Acid	112-80-1	204-007-1	1 - 5*
MAGNESIUM STEARATE NF(VEGETABLE SOURCE)	557-04-0	209-150-3	0.1 - 1*
Trospium Chloride	10405-02-4	233-875-4	0.1 - 1*
Titanium Dioxide	1317-70-0	215-280-1	0.1 - 1*
MICROCRYSTALLINE CELLULO(AVICEL PH102)	9004-34-6	232-674-9	0.1 - 1*
POVIDONE USP(PLASDONE K-29-32)	9003-39-8	N/A	<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*
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

General advice Immediate medical attention is required.

Eye contact Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately.

Skin Contact Immediate medical attention is required. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation Immediate medical attention is required. Remove to fresh air. If not breathing, give artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.

Ingestion Do NOT induce vomiting. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person. Drink plenty of water.

Chemical Name	**Note to physicians**
Donepezil HCL	Overdosage with cholinesterase inhibitors can result in cholinergic crisischaracterized by severe nausea, vomiting, salivation, sweating, bradycardia,hypotension, respiratory depression, collapse and convulsions. Increasingmuscle weakness is a possibility and may result in death if respiratorymuscles are involved. Tertiary anticholinergics such as atropine may beused as an antidote for ARICEPT overdosage. Intravenous atropine sulfatetitrated to effect is recommended: an initial dose of 1.0 to 2.0 mg IV withsubsequent doses based upon clinical response.
Memantine Hydrochloride	Conditions that raise urine pH may decrease urinary elimination of Memantine, resulting in increased plasma levels of memantine.

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 protective equipment as required. Keep people away from and upwind of spill/leak.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. See Section 12 for additional ecological information.

Methods for containment Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Advice on safe handling Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.

Storage Conditions Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children.

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/m³)
Colloidal Silica Anhydrous 7631-86-9	N/A	(vacated) TWA: 6 mg/m³ <1% Crystalline silica TWA: 20 mppcf : (80)/(% SiO2) mg/m³ TWA	IDLH: 3000 mg/m³ TWA: 6 mg/m³	N/A
Donepezil HCL 120011-70-3	N/A	N/A	N/A	17
CONFECTIONERS SUGAR 6XWITH CORN STARCH 57-50-1	TWA: 10 mg/m³	TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction	TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust	N/A

Memantine Hydrochloride 41100-52-1	N/A	N/A	N/A	67
CORN STARCH NF 9005-25-8	TWA: 10 mg/m³	TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction	TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust	N/A
Tetracycline 60-54-8	N/A	N/A	N/A	250.00
Asenapine 85650-56-2	N/A	N/A	N/A	2
TALC USP(1656) 14807-96-6	TWA: 2 mg/m³ particulate matter containing no asbestos and <1% crystalline silica, respirable particulate matter	(vacated) TWA: 2 mg/m³ respirable dust <1% Crystalline silica, containing no Asbestos TWA: 20 mppcf if 1% Quartz or more;use Quartz limit	IDLH: 1000 mg/m³ TWA: 2 mg/m³ containing no Asbestos and <1% Quartz respirable dust	N/A
MAGNESIUM STEARATE NF(VEGETABLE SOURCE) 557-04-0	TWA: 10 mg/m³ inhalable particulate matter TWA: 3 mg/m³ respirable particulate matter TWA: 10 mg/m³ inhalable particulate matter except stearates of toxic metals TWA: 3 mg/m³ respirable particulate matter except stearates of toxic metals	N/A	N/A	N/A
Trospium Chloride 10405-02-4	N/A	N/A	N/A	100 ug/m^3
MICROCRYSTALLINE CELLULO(AVICEL PH102) 9004-34-6	TWA: 10 mg/m³	TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction (vacated) TWA: 5 mg/m³ (vacated) STEL: 10 mg/m³	TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust TWA: 1 mg/m³	N/A
STEARIC ACID NF 57-11-4	TWA: 10 mg/m³ inhalable particulate matter TWA: 3 mg/m³ respirable particulate matter	N/A	N/A	N/A
FERRIC OXIDE NF (RED 30) 1309-37-1	TWA: 5 mg/m³ respirable particulate matter	TWA: 10 mg/m³ fume TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 10 mg/m³ fume and total dust Iron oxide (vacated) TWA: 5 mg/m³ respirable fraction regulated under Rouge	IDLH: 2500 mg/m³ Fe dust and fume TWA: 5 mg/m³ Fe dust and fume	N/A
White Cresin Wax 8002-74-2	TWA: 2 mg/m³ fume	(vacated) TWA: 2 mg/m³	TWA: 2 mg/m³ fume	N/A

NIOSH IDLH Immediately Dangerous to Life or Health

Other Information Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

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

Physical state	Solid	**Appearance**	Capsule
Color	No information available	**Odor**	No information available
Odor threshold	No information available		

Property	**Values**
pH	No information available
Melting point/freezing point	No information available
Boiling point / boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	No information available
Water solubility	No information available
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available

Other Information

Molecular weight	No information available
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

10. STABILITY AND REACTIVITY

Reactivity
Not defined As Reactive substance

Chemical stability
Stable under normal conditions.

Possibility of Hazardous Reactions
None under normal processing.
Conditions to avoid
Aerosol formation.
Incompatible materials
None known based on information supplied.
Hazardous Decomposition Products
None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

Chemical Name	Inhalation	Eye contact	Skin Contact	Ingestion
Donepezil HCL	Inhalation of this compound may irritate the nose, throat, andlungs. No information is available on other possible effects.	Contact with the eyes of airborne dusts generated by this product may cause mild to moderate irritation, redness, and tearing.	Contact with the skin may cause irritation. Prolonged orrepeated skin contact may cause dermatitis (dry, red skin).	Ingestion is not a significant route of occupational overexposure.If swallowed, irritation of the gastrointestinal tract may occur with nausea,vomiting, and diarrhea.
Tetracycline	Irritating to respiratory system.	Irritating to eyes.	Irritating to skin.	See Symptoms for more information.
Pirenoxine	See Symptoms for more information.	Eye contact may result in redness, pain or severe eye damage. Inhalation may cause irritation of the lungs and respiratory system.	Skin contact may result in inflammation characterized by itching, scaling, reddening, blistering, pain or dryness.	May cause irritation.
Asenapine	Move to fresh air. If symptoms persist, call a physician.	See Symptoms for more information.	See Symptoms for more information.	See Symptoms for more information.
Trospium Chloride	If airborne dusts generated by this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.	Contact with the eyes of airborne dusts generated by this compound may cause mild to moderate irritation, redness, and tearing (mechanical irritation).	In therapeutic use, this compound has caused swelling of the skin, rash and anaphylactic reactions. Angioedema of the face, lips, tongue and/or larynx has been reported with therapetuic use of Trospium. Angioedema associated with upper airway swelling may be life threatening. May cause irritation to skin. Prolonged or repeated skin contact may caus dermatitis (dry, red skin).	If this compound is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with 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.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Colloidal Silica Anhydrous	> 5000 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 2.2 mg/L (Rat) 1 h
Medium Chain Triglycerides	> 5000 mg/kg (Rat)	N/A	N/A
ETHYLCELLULOSE NF ETHOCEL 100	> 5 g/kg (Rat)	> 5 g/kg (Rabbit)	N/A
Donepezil HCL	32.6 mg/kg (rat)	N/A	N/A
CONFECTIONERS SUGAR 6XWITH CORN STARCH	= 29700 mg/kg (Rat)	N/A	N/A
Memantine Hydrochloride	328 mg/kg Oral Rat (Female)	N/A	N/A
UREA USP	= 8471 mg/kg (Rat)	N/A	N/A
Tetracycline	= 807 mg/kg (Rat)	N/A	N/A
Sodium salicylate	= 930 mg/kg (Rat)	N/A	N/A
Pirenoxine	>10,000 mg/kg Oral Rat	N/A	N/A
Oleic Acid	= 25 g/kg (Rat)	N/A	N/A

Trospium Chloride	= 1510 mg/kg (Rat)	N/A	N/A
MICROCRYSTALLINE CELLULO(AVICEL PH102)	> 5 g/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m³ (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/m³ (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
Donepezil HCL	Not mutagenic in the standard battery of tests.	Not suspected of being a human carcinogen.	This product does not contain any known or suspected reproductive hazards.	No information available
Memantine Hydrochloride	Not mutagenic in the standard battery of tests.	Animal studies in mice and rats have not shown carcinogenicity.	Studies in rats have not shown fertility impairment. Decreased pup weights and an increase in incompletely ossified vertebrae was observed at slightly maternally toxic doses with the NOEL of approximately 3 times the maximum recommended human therapeutic dose.	It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this drug is administered to nursing mothers.
Tetracycline	Mutagenicity tests have not been conducted, however, positive results in vitro mammalian cell assays have been reported for related anti-bacterial drugs (tetracycline).	Animal studies in mice and rats have not shown carcinogenicity.	The therapeutic use of tetracyclines during the last half of pregnancy may cause permanent discoloration of teeth, incomplete development or lack of enamel, and inhibition of skeletal growth in the fetus. Fatty infiltration of the liver, leading to damage or failure, may occur in pregnant women.	No information available
Sodium salicylate	Not Suspected of being a Mutagen.	This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.	No information available.	This product is excreted in human breast milk. There is a potential for serious adverse effects in a nursing infant. Patient should stop nursing if this product is being used due to the potential for serious adverse effects to the nursing infant.
Pirenoxine	No information available.	Not listed by IARC, NTP, or USOSHA.	No information available.	No information available
Asenapine	Negative for genotoxicity in vitro and in vivo tests.	Chronic Exposure or Carcinogenicity/ In a lifetime carcinogenicity study in CD-1 mice asenapine was administered subcutaneously at doses up to those resulting in plasma levels (AUC) estimated to be 5 times those in humans receiving the maximum recommended human dose (MRHD) of 10 mg twice daily. The incidence of	Not teratogenic in rats or rabbits. Studies in rats have not shown fertility impairment. increases in post-implantation loss and early pup deaths were seen at all doses, and decreases in subsequent pup survival and weight gain were seen at the two higher doses in rats.	No information available

		malignant lymphomas was increased in female mice, with a no-effect dose resulting in plasma levels estimated to be 1.5 times those in humans receiving the MRHD. The mouse strain used has a high and variable incidence of malignant lymphomas, and the significance of these results to humans is unknown. There were no increases in other tumor types in female mice. In male mice, there were no increases in any tumor type.		
Oleic Acid	Not Suspected of being a Mutagen.	Not suspected of being a human carcinogen.	Not suspected of being a reproductive hazard.	No information available
Trospium 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 Central nervous system, Central Vascular System (CVS), Eyes, Gastrointestinal tract (GI), Respiratory system, Skin.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 29% 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) 216 mg/kg

ATEmix (dermal) 7481 mg/kg

ATEmix (inhalation-dust/mist) 2.6 mg/l

12. ECOLOGICAL INFORMATION

Ecotoxicity

63% of the mixture consists of components(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
Colloidal Silica Anhydrous 7631-86-9	440: 72 h Pseudokirchneriella subcapitata mg/L EC50	5000: 96 h Brachydanio rerio mg/L LC50 static	7600: 48 h Ceriodaphnia dubia mg/L EC50
Medium Chain Triglycerides 73398-61-5	N/A	N/A	2.2: 24 h Daphnia magna mg/L EC50
UREA USP 57-13-6	N/A	16200 - 18300: 96 h Poecilia reticulata mg/L LC50	10000: 24 h Daphnia magna Straus mg/L EC50 3910: 48 h Daphnia magna mg/L EC50 Static
Tetracycline 60-54-8	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.	220	N/A
Sodium salicylate 54-21-7	N/A	1270 - 1470: 96 h Pimephales promelas mg/L LC50 flow-through	N/A
TALC USP(1656) 14807-96-6	N/A	100: 96 h Brachydanio rerio g/L LC50 semi-static	N/A
Oleic Acid 112-80-1	N/A	205: 96 h Pimephales promelas mg/L LC50 static	N/A

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient

Donepezil HCL 120011-70-3	This compound has not been tested for persistence or biodegradability	Based on the BCF, the potential for bioaccumulation in aquatic organisms is high.	This product has not been tested for mobility in soil	Log P = 4.708 (predict.)
Memantine Hydrochloride 41100-52-1	N/A	Based on the BCF, the potential for bioaccumulation in aquatic organisms is high.	Low mobility in soil	3.28
UREA USP 57-13-6	N/A	N/A	N/A	-1.59
Sodium salicylate 54-21-7	N/A	N/A	N/A	2.26
Asenapine 85650-56-2	N/A	Based on the BCF, the potential for bioaccumulation in aquatic organisms is high.	Immobile	4.77
Trospium 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

IATA Not regulated

IMDG Not regulated

ADR Not regulated

ADN Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA Not Listed
DSL/NDSL Not Listed
EINECS/ELINCS 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

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen This product contains one or more substances which are classified by IARC as

carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B)

Chemical Name	ACGIH	IARC	NTP	OSHA
Colloidal Silica Anhydrous 7631-86-9	-	Group 3	-	-
TALC USP(1656) 14807-96-6	-	Group 3	-	X
MICROCRYSTALLINE CELLULO(AVICEL PH102) 9004-34-6	-	Group 1	Known	X
POVIDONE USP(PLASDONE K-29-32) 9003-39-8	-	Group 3	-	-
FERRIC OXIDE NF (RED 30) 1309-37-1	-	Group 3	-	-
COLOIDAL SILICON DIOXIDE(CAB-O-SIL GRADE M-5P) 112945-52-5	-	Group 3	-	-

IARC (International Agency for Research on Cancer)
Not classifiable as a human carcinogen

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

Acute health hazard	Yes
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	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

Chemical Name	California Proposition 65
Tetracycline - 60-54-8	Developmental
MICROCRYSTALLINE CELLULO(AVICEL PH102) - 9004-34-6	Carcinogen

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Colloidal Silica Anhydrous 7631-86-9	-	X	X
Oleic Acid 112-80-1	-	-	X
TALC USP(1656) 14807-96-6	X	X	X

16. OTHER INFORMATION

Revision Date	02-Oct-2018
Revision Note	No information available

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End of Safety Data Sheet