



SAFETY DATA SHEET

Revision Date 16-Jul-2019

Version 3

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

Product identifier

Product Name Microzide

Other means of identification

Product Code FG00174

Synonyms Hydrochlorothiazide Capsules

Recommended use of the chemical and restrictions on use

Recommended Use Anti-hypertensive

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)

Carcinogenicity	Category 2
Effects on or via lactation	Yes

Label elements

Emergency Overview

Warning

Hazard statements

H351 - Suspected of causing cancer
H362 - May cause harm to breast-fed children



Appearance Capsule	Physical state Solid	Odor No information available
Chemical Name HYDROCHLOROTHIAZIDE	Symptoms The following adverse reactions have been reported and, within each category, are listed in order of decreasing severity: weakness, hypotension including orthostatic hypotension (may be aggravated by alcohol, barbiturates, narcotics or antihypertensive drugs), pancreatitis, jaundice (intrahepatic cholestatic jaundice), diarrhea, vomiting, sialadenitis, cramping, constipation, gastric irritation, nausea, anorexia, aplastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia, anaphylactic reactions, necrotizing angiitis (vasculitis and cutaneous vasculitis), respiratory distress including pneumonitis and pulmonary edema, photosensitivity, fever, urticaria, rash, purpura, electrolyte imbalance, hyperglycemia, glycosuria, hyperuricemia, muscle spasm, vertigo, paresthesias, dizziness, headache, restlessness, renal failure, renal dysfunction, interstitial nephritis, erythema multiforme including Stevens-Johnson syndrome, exfoliative dermatitis including toxic epidermal necrolysis, alopecia, transient blurred vision, xanthopsia, impotence. The most common adverse reactions are dry mouth, constipation, and headache. The most common symptoms seen in therapeutic use include: nausea, diarrhea, insomnia, vomiting, muscle cramp, fatigue and anorexia.	
Trospium Chloride Donepezil HCL	Possible eye, skin, gastrointestinal and/or respiratory tract irritation. Possible allergic reaction to material if inhaled, ingested or in contact with skin. Overdose effects from ingestion of large amounts include abdominal cramps, flatulence, and fecal impaction. Most common are dizziness, headache, confusion and constipation	
POVIDONE USP(PLASDONE K-29-32)	Possible eye, skin, gastrointestinal and/or respiratory tract irritation. Possible allergic reaction to material if inhaled, ingested or in contact with skin. Overdose effects from ingestion of large amounts include abdominal cramps, flatulence, and fecal impaction. Most common are dizziness, headache, confusion and constipation	
Memantine Hydrochloride		
Chemical Name HYDROCHLOROTHIAZIDE Trospium Chloride	Medical Conditions Aggravated by Exposure Anuria. Known hypersensitivity to this product or to other sulfonamide-derived drugs. This medication is contraindicated in patients with: urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, known hypersensitivity to the drug or its ingredients; angioedema, rash and anaphylactic reaction have been reported. When administered for therapeutic use, pre-existing asthma, ulcers, cardiac abnormalities, hepatic, bladder and neurological conditions may be aggravated by exposure	
Donepezil HCL	Known hypersensitivity to this medication	
POVIDONE USP(PLASDONE K-29-32) Memantine Hydrochloride	Contraindication include hypersensitivity to any component of this product hepatic impairment	

Precautionary statements

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

P281 - Use personal protective equipment as required

P405 - Store locked up

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

P201 - Obtain special instructions before use

P260 - Do not breathe dusts or mists

P263 - Avoid contact during pregnancy/while nursing

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

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

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

Other Information

Unknown Acute Toxicity

2.15% 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-%
HYDROCHLOROTHIAZIDE	58-93-5	200-403-3	30 - 60*
CORN STARCH NF	9005-25-8	232-679-6	1 - 5*
Tropium Chloride	10405-02-4	233-875-4	0.1 - 1*
Donepezil HCL	120011-70-3	N/A	0.1 - 1*
POVIDONE USP(PLASDONE K-29-32)	9003-39-8	N/A	0.1 - 1*
TALC USP(1656)	14807-96-6	238-877-9	0.1 - 1*
Memantine Hydrochloride	41100-52-1	255-219-6	0.1 - 1*
Oleic Acid	112-80-1	204-007-1	<0.1*

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

4. FIRST AID MEASURES

First aid measures

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

Chemical Name
HYDROCHLOROTHIAZIDE

Note to physicians

This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure. Suggested measures include induction of emesis and/or gastric lavage, if ingestion is recent, and correction of dehydration, electrolyte imbalance, hepatic coma, and hypotension by established procedures. If digitalis has also been administered, hypokalemia may accentuate cardiac arrhythmias. Tropium chloride is contraindicated in patients with urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, and known hypersensitivity to the drug or its ingredients. Angioedema, rash and anaphylactic reaction have been reported. Overdosage with cholinesterase inhibitors can result in cholinergic crisis characterized by severe nausea, vomiting, salivation, sweating, bradycardia, hypotension, respiratory depression, collapse and convulsions. Increasing muscle weakness is a possibility and may result in death if respiratory muscles are involved. Tertiary anticholinergics such as atropine may be used as an antidote for ARICEPT overdose. Intravenous atropine sulfate titrated to effect is recommended: an initial dose of 1.0 to 2.0 mg IV with subsequent doses based upon clinical response. Conditions that raise urine pH may decrease urinary elimination of Memantine, resulting in increased plasma levels of memantine.

Tropium Chloride

Donepezil HCL

Memantine Hydrochloride

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

See Section 12 for additional ecological information.

Methods for containment

Prevent further leakage or spillage if safe to do so.

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. 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 ³)
HYDROCHLOROTHIAZIDE 58-93-5	N/A	N/A	N/A	60 ug/m ³
CORN STARCH NF 9005-25-8	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust	N/A
Tropium Chloride 10405-02-4	N/A	N/A	N/A	100 ug/m ³
Donepezil HCL 120011-70-3	N/A	N/A	N/A	17
TALC USP(1656) 14807-96-6	TWA: 2 mg/m ³ particulate matter containing no asbestos and <1% crystalline silica, respirable particulate matter	(vacated) TWA: 2 mg/m ³ respirable dust <1% Crystalline silica, containing no Asbestos TWA: 20 mppcf if 1% Quartz or more;use Quartz limit	IDLH: 1000 mg/m ³ TWA: 2 mg/m ³ containing no Asbestos and <1% Quartz respirable dust	N/A

Memantine Hydrochloride 41100-52-1	N/A	N/A	N/A	67
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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		

<u>Property</u>	<u>Values</u>
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
HYDROCHLOROTHIAZIDE	Inhalation of airborne dusts generated by this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.	Contact with the eyes of airborne dusts generated by this compound may cause mild to moderate irritation, redness, and tearing (mechanical irritation).	Contact with the skin may cause mild irritation, which is alleviated upon rinsing. Prolonged or repeated skin contact may cause dermatitis (dry, red skin).	Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause adverse symptoms. Symptoms of ingestion overexposure may include electrolyte depletion, dehydration, nausea, vomiting, and diarrhea. Symptoms of prolonged or repeated ingestion, as may occur when poor industrial hygiene is practiced, may include those described for "Other Potential Health Effects". Individuals who have had allergic reactions to products containing Hydrochlorothiazide, other sulfonamide-derived drugs, Corn Starch, or any of the other ingredients in this product may experience allergic reactions to this product.
Tropisium Chloride	If airborne dusts generated by this product are inhaled, remove victim to fresh air. If	Contact with the eyes of airborne dusts generated by this compound may cause	In therapeutic use, this compound has caused swelling of the skin, rash and	If this compound is swallowed, CALL PHYSICIAN OR POISON

	necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.	mild to moderate irritation, redness, and tearing (mechanical irritation).	anaphylactic reactions. Angioedema of the face, lips, tongue and/or larynx has been reported with therapeutic use of Trospium. Angioedema associated with upper airway swelling may be life threatening. May cause irritation to skin. Prolonged or repeated skin contact may cause dermatitis (dry, red skin).	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.
Donepezil HCL	Inhalation of this compound may irritate the nose, throat, and lungs. 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 or repeated 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.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
HYDROCHLOROTHIAZIDE	= 2750 mg/kg (Rat)	N/A	N/A
Trospium Chloride	= 1510 mg/kg (Rat)	N/A	N/A
Donepezil HCL	32.6 mg/kg (rat)	N/A	N/A
POVIDONE USP(PLASDONE K-29-32)	= 100 g/kg (Rat)	N/A	N/A
Memantine Hydrochloride	328 mg/kg Oral Rat (Female)	N/A	N/A
Oleic Acid	= 25 g/kg (Rat)	N/A	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
HYDROCHLOROTHIAZIDE	Hydrochlorothiazide was not genotoxic in vitro in the Ames mutagenicity assay of Salmonella typhimurium strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538 and in the Chinese Hamster Ovary (CHO) test for chromosomal aberrations, or in vivo in assays using mouse germinal cell chromosomes, Chinese hamster bone marrow chromosomes, and the Drosophila sex-linked recessive lethal trait gene. Positive test results were obtained only in the in vitro CHO Sister Chromatid Exchange (clastogenicity) and in the Mouse Lymphoma Cell(mutagenicity) assays, using concentrations of hydrochlorothiazide from 43 to 1300 mcg/mL, and in the Aspergillus nidulans non-disjunction assay at an unspecified concentration.	The National Toxicology Program (NTP) uncovered no evidence of a carcinogenic potential of hydrochlorothiazide in female mice (at doses of up to approximately 600 mg/kg/day) or in male and female rats (at doses of approximately 100 mg/kg/day). The NTP, however, found equivocal evidence for hepato carcinogenicity in male mice.	Animal studies in mice and rats have not shown teratogenicity, fertility impairment or harm to the fetus. Thiazides cross the placental barrier and appear in cord blood. There is a risk of fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions that have occurred in adults.	Thiazides are excreted in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue hydrochlorothiazide, taking into account the importance of the drug to the mother
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	Detectable amounts of this compound have been identified in the milk of nursing women receiving

			fetus.	this drug. Caution should be exercised when taking this compound is administered to nursing women.
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
POVIDONE USP(PLASDONE K-29-32)	No information available.	Not suspected of being a human carcinogen.	No information available.	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.
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

Target Organ Effects Eyes, Respiratory system, Skin.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 2.15% 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) 3595 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

88.15% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
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
HYDROCHLOROTHIAZIDE 58-93-5	N/A	N/A	No information available	no data available
Tropium Chloride 10405-02-4	No information available	No information available	No information available	Log P = 0.70
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

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
HYDROCHLOROTHIAZIDE 58-93-5	-	Group 2B	-	X
POVIDONE USP(PLASDONE K-29-32) 9003-39-8	-	Group 3	-	-
TALC USP(1656) 14807-96-6	-	Group 3	-	X

IARC (International Agency for Research on Cancer)
Group 1 - Carcinogenic to Humans
Group 2B - Possibly Carcinogenic to Humans
Not classifiable as a human carcinogen
NTP (National Toxicology Program)
Known - Known Carcinogen
OSHA (Occupational Safety and Health Administration of the US Department of Labor)
X - Present

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	No
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 contains the following Proposition 65 chemicals

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

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
MICROCRYSTALLINE CELLULO(AVICEL PH102) 9004-34-6	X	X	X
TALC USP(1656) 14807-96-6	X	X	X
FERRIC OXIDE NF (RED 30) 1309-37-1	X	X	X
White Cresin Wax 8002-74-2	X	X	X
Oleic Acid 112-80-1	-	-	X

16. OTHER INFORMATION

Revision Date 16-Jul-2019
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