



Material Safety Data Sheet

Issuing Date 22-May-2013

Revision Date 09-Mar-2012

Revision Number 2

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name 571-FEXOFENADINE HCL 180mg TABLETS

Recommended Use Pharmaceutical.

Supplier Address

Perrigo Company
515 Eastern Ave
Allegan
MI
49010
US
Phone:888.464.2986
Contact:Bill Lackey
Email:blackey@perrigo.com
Contact Phone616.673.9375

2. HAZARDS IDENTIFICATION

CAUTION!

Emergency Overview

May cause eye irritation

May be harmful if swallowed in amounts above the therapeutic dose

Consumers: Refer to the package insert for consumer-specific information about the directional use and effects of this product.

Only information about the ingredients that are expected to contribute to the potential health effects of the product are included in this MSDS.

Do not use if printed seal under cap is broken or missing

Appearance Tan

Physical State Solid.

Odor No information available

OSHA Regulatory Status

Over-the counter drugs in their final form as sold to the consumer are considered exempt under the criteria of the Federal OSHA Communication Standard 29CFR1910.1200. However, if exposure may occur in the industrial setting, outside of personal use, the occupational exposure limits may be exceeded and may be considered hazardous.

Potential Health Effects

Principle Routes of Exposure

Skin contact. Ingestion.

Adults and children 12 years of age and over: take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours.

Children under 12 years of age: do not use.

Adults 65 years of age and older and consumers with kidney disease: ask a doctor before use.

Acute Toxicity

Eyes

Skin

Non-irritating during normal use. Dust contact with the eyes can lead to mechanical irritation. Non-irritating during normal use. Contact with dust can cause mechanical irritation or drying of the skin.

Inhalation

Inhalation of dust in high concentration may cause irritation of respiratory system.

Ingestion	No known effect when taken as indicated. Ingestion at levels above recommended values may be harmful. See package insert for further information.
Chronic Effects	Titanium dioxide has been classified by the International Agency for Research on Cancer (IARC) as possibly carcinogenic to humans (Group 2B) by inhalation. This product contains titanium dioxide in a non-respirable form. Inhalation of titanium dioxide is unlikely to occur from exposure to this product.
Aggravated Medical Conditions	Gastrointestinal tract. Kidney disorders. If pregnant or breast feeding ask a health professional before use.
Environmental Hazard	See Section 12 for additional Ecological Information.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %
Lactose	63-42-3	30-60
Fexofenadine hydrochloride	153439-40-8	15-40
Microcrystalline cellulose	9004-53-9	15-40
Croscarmellose sodium	74811-65-7	7-13
Magnesium stearate	557-04-0	1 - 5
Povidone	9003-39-8	1 - 5
Hydroxypropyl methylcellulose	8063-82-9	1 - 5
Silica	112945-52-5	0.1 - 1
Titanium dioxide	13463-67-7	0.1 - 1
Polyethylene glycol	25322-68-3	0.1 - 1
Supplier Trade Secret	Proprietary	< 0.1
Iron oxide yellow	51274-00-1	< 0.1
Supplier Trade Secret	Proprietary	< 0.1

4. FIRST AID MEASURES

Eye Contact	Rinse thoroughly with plenty of water, also under the eyelids. If symptoms persist, call a physician.
Skin Contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
Inhalation	Move to fresh air. If symptoms persist, call a physician.
Ingestion	Do NOT induce vomiting. Drink plenty of water. If symptoms persist, call a physician. If large quantities of this material are swallowed, call a physician immediately.
Notes to Physician	Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Not flammable.
Flash Point	Not determined.
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Hazardous Combustion Products	Carbon oxides. Nitrogen oxides (NOx). Chlorine compounds.
Explosion Data	
Sensitivity to Mechanical Impact	No.

Sensitivity to Static Discharge No.

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.

NFPA **Health Hazard** 1 **Flammability** 1 **Stability** 0 **Physical and Chemical Hazards** -

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Avoid contact with eyes.
Environmental Precautions	Refer to protective measures listed in Sections 7 and 8.
Methods for Containment	Prevent further leakage or spillage if safe to do so.
Methods for Cleaning Up	Use personal protective equipment. Pick up and transfer to properly labeled containers. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes.
Storage	Keep container tightly closed. Store in original container. Store at room temperature. Keep out of the reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Magnesium stearate 557-04-0	TWA: 10 mg/m ³		
Hydroxypropyl methylcellulose 8063-82-9		(vacated) Ceiling: 5 mg/m ³ Ceiling: 5 mg/m ³ Mn	IDLH: 500 mg/m ³ Mn TWA: 1 mg/m ³ Mn STEL: 3 mg/m ³ Mn
Titanium dioxide 13463-67-7	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust (vacated) TWA: 10 mg/m ³ total dust	IDLH: 5000 mg/m ³
Supplier Trade Secret	TWA: 1 mg/m ³ Fe	(vacated) TWA: 1 mg/m ³ Fe	TWA: 1 mg/m ³ Fe

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value. OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits. NIOSH IDLH: Immediately Dangerous to Life or Health.

Other Exposure Guidelines

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

Engineering Measures

None under normal use conditions. For home use. Ensure that eyewash stations and safety showers are close to the workstation location. Apply technical measures to comply with the occupational exposure limits.

Personal Protective Equipment

Eye/Face Protection

None required for consumer use. Safety glasses with side shields are recommended for medical or industrial exposures.

Skin and Body Protection

None required for consumer use. Gloves and lab coats are recommended for medical or industrial exposures.

Respiratory Protection

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke. Remove and wash contaminated clothing before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Tan.	Odor	No information available.
Odor Threshold	No information available	Physical State	Solid
pH	UNKNOWN		
Flash Point	No information available.	Autoignition Temperature	No information available
Decomposition Temperature	No information available	Boiling Point/Range	No information available
Melting Point/Range	No information available		
Flammability Limits in Air	No information available	Explosion Limits	No information available
Water Solubility	Soluble in water.	Solubility	No information available
Evaporation Rate	No information available	Vapor Pressure	No data available
Vapor Density	No data available	Partition Coefficient: n-octanol/water	

10. STABILITY AND REACTIVITY

Stability	Stable under recommended storage conditions.
Incompatible Products	Strong oxidizing agents.
Conditions to Avoid	None known.
Hazardous Decomposition Products	Carbon oxides. Nitrogen oxides (NOx). Chlorine compounds.
Hazardous Polymerization	Hazardous polymerization does not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Product Information

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Lactose	10 g/kg (Rat)	-	-
Povidone	= 100 g/kg (Rat)	-	-
Silica	= 3160 mg/kg (Rat)	-	-
Titanium dioxide	10000 mg/kg (Rat)	-	-
Polyethylene glycol	= 28 g/kg (Rat)	> 20 g/kg (Rabbit)	-

Chronic Toxicity

Chronic Toxicity

Titanium dioxide has been classified by the International Agency for Research on Cancer (IARC) as possibly carcinogenic to humans (Group 2B) by inhalation. This product contains titanium dioxide in a non-respirable form. Inhalation of titanium dioxide is unlikely to occur from exposure to this product.

Carcinogenicity

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical Name	ACGIH	IARC	NTP	OSHA
Povidone		Group 3		
Silica		Group 3		
Titanium dioxide		Group 2B		X

IARC: (International Agency for Research on Cancer)

Group 2B - Possibly Carcinogenic to Humans

Group 3 - Not Classifiable as to Carcinogenicity in Humans

OSHA: (Occupational Safety & Health Administration)

X - Present

Target Organ Effects

Kidney. Respiratory system. Gastrointestinal tract (GI).

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Polyethylene glycol		LC50: >5000 mg/L Carassius auratus 24 h	EC50 = 100000 mg/L 15 min	

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods

This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging

Dispose of in accordance with local regulations.

California Hazardous Waste Codes 311

This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical Name	California EHW	California Carc	California Hazardous Waste	California Waste - Part 2
Hydroxypropyl methylcellulose			Toxic	STLC (for PBTs): 250 mg/L TTLC (for PBTs): 5000 mg/kg

14. TRANSPORT INFORMATION

DOT NOT REGULATED

TDG Not regulated

MEX Not regulated

ICAO Not regulated

IATA Not regulated

IMDG/IMO Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA Exempt
 DSL Not determined

U.S. Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372:

Chemical Name	CAS-No	Weight %	SARA 313 - Threshold Values %
Hydroxypropyl methylcellulose	8063-82-9	1 - 5	1.0

SARA 311/312 Hazard Categories

Acute Health Hazard Yes
 Chronic Health Hazard Yes
 Fire Hazard No
 Sudden Release of Pressure Hazard No
 Reactive Hazard No

Clean Water Act

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42):

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Hydroxypropyl methylcellulose		X		

Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (see 40 CFR 61)

This product contains the following substances which are listed hazardous air pollutants (HAPS) under Section 112 of the Clean Air Act:

Chemical Name	CAS-No	Weight %	HAPS data	VOC Chemicals	Class 1 Ozone Depletors	Class 2 Ozone Depletors
Hydroxypropyl methylcellulose	8063-82-9	1 - 5				

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302):

U.S. State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals:

Chemical Name	CAS-No	California Prop. 65
Titanium dioxide	13463-67-7	x

U.S. State Right-to-Know Regulations

Chemical Name	Massachusetts	New Jersey	Pennsylvania	Illinois	Rhode Island
Titanium dioxide	X	X	X		

Chemical Name	Massachusetts	New Jersey	Pennsylvania	Illinois	Rhode Island
Hydroxypropyl methylcellulose			X	X	X

International Regulations

Mexico - Grade No information available.

Chemical Name	Carcinogen Status	Exposure Limits
Supplier Trade Secret		Mexico: TWA 1 mg/m ³ Mexico: STEL 2 mg/m ³
Titanium dioxide		Mexico: TWA= 10 mg/m ³ Mexico: STEL= 20 mg/m ³

Canada

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

WHMIS Hazard Class

Not regulated under CEPA

Not subject to WHMIS classification

16. OTHER INFORMATION

Prepared By Product Stewardship
23 British American Blvd.
Latham, NY 12110
1-800-572-6501

Issuing Date 22-May-2013

Revision Date 09-Mar-2012

Revision Note No information available

General Disclaimer

This MSDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to the manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purposes(s).

End of Safety Data Sheet