



SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Fexofenadine HCl 180 mg Geltabs

Synonyms: 3R6

Manufacturer Name: Perrigo Company
Address: 515 Eastern Avenue
Allegan, MI 49010 USA

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986 (U.S. calls)
+1 760-476-3962 Code 333304 (International calls)

Email Address: SDSRequest@perrigo.com

Recommended use: Human drug

Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not Hazardous

Label Elements

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Fexofenadine Hydrochloride	153439-40-8 / 138452-21-8	20-30%
Lactose Monohydrate	64044-51-5	Proprietary
Microcrystalline Cellulose	9004-34-6	Proprietary
Croscarmellose Sodium	74811-65-7	Proprietary
Colloidal Silicon Dioxide	112945-52-5	Proprietary
Magnesium Stearate	557-04-0	Proprietary
Pregelatinized Starch	9005-25-8	Proprietary
Polyethylene Glycol	25322-68-3	Proprietary
Titanium Dioxide (bound in coating matrix)	13463-67-7	Proprietary
Talc	14807-96-6	Proprietary
Polyvinyl Alcohol	9002-89-5	Proprietary
Gelatin	9000-70-8	Proprietary
Glycerin	56-81-5	Proprietary
Stearic Acid	57-11-4	Proprietary
Maltitol	68425-17-2	Proprietary
Medium Chain Triglycerides	438544-49-1	Proprietary

Lecithin	8002-43-5	Proprietary
Pharmaceutical Ink	Mixture	Proprietary
D&C Red #27 Aluminum Lake	13473-26-2	Proprietary
FD&C Blue #1 Aluminum Lake	15792-67-3	Proprietary

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

4. FIRST-AID MEASURES

Inhalation: Remove victim to fresh air. If irritation occurs or symptoms develop, get medical attention.

Skin contact: In the case of contact with crushed or broken geltabs, remove contaminated clothing. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: In the case of unintended ingestion, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention if any adverse effects occur or for overdose.

Most important symptoms/effects, acute and delayed: Dust may cause eye irritation. Inhalation of dust from broken geltabs may cause upper respiratory tract irritation and symptoms similar to ingestion. Swallowing amounts above the recommended dosage may cause gastrointestinal effects.

Indication of immediate medical attention and special treatment, if necessary: Medical attention is recommended for large unintended ingestion.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

Specific hazards arising from the chemical: Geltabs are not a fire hazard but may burn under fire conditions. Fine dust from crushed geltabs will present a dust explosion hazard.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8. If geltabs are damaged, respiratory protection may be required. Avoid generating airborne dust during cleanup. If dust is present, eliminate all sources of ignition.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Collect using methods that avoid the generation of dust and damage to geltabs (scoop up carefully) and place in appropriate container for disposal. Clean area thoroughly. If dust is present, do not use vacuum unless explosion-proof.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of dust. If geltabs are damaged, avoid contact with eyes, skin and clothing and avoid breathing dust. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging in a secure location.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Exposure guidelines:**

Fexofenadine Hydrochloride	700 ug/m3 TWA (Perrigo OEB2)
Lactose Monohydrate	None Established
Microcrystalline Cellulose	10 mg/m3 TWA ACGIH TLV 5 mg/m3 (respirable) 15 mg/m3 (total dust) TWA OSHA PEL
Croscarmellose Sodium	None Established
Colloidal Silicon Dioxide	80 mg/m3/%SiO2 TWA OSHA PEL
Magnesium Stearate	10 mg/m3 (total dust) TWA ACGIH TLV
Polyethylene Glycol	None Established
Titanium Dioxide (bound in coating matrix)	10 mg/m3 TWA ACGIH TLV 15 mg/m3 (total dust) TWA OSHA PEL
Talc	2 mg/m3 (respirable) TWA ACGIH TLV 20 mppcf TWA OSHA PEL
Polyvinyl Alcohol	None Established
Gelatin	None Established
Glycerin	5 mg/m3 (respirable) 15 mg/m3 (total dust) TWA OSHA PEL
Stearic Acid	None Established
Maltitol	None Established
Medium Chain Triglycerides	None Established
Lecithin	None Established
Pharmaceutical Ink	None Established
D&C Red #27 Aluminum Lake	None Established
FD&C Blue #1 Aluminum Lake	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: Impervious gloves recommended for handling damaged geltabs.

Eye protection: Chemical safety goggles recommended for handling damaged geltabs.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Capsule shaped gelatin enrobed tablet, white to off-white on one side, purple on the other

Odor: None

Odor threshold: Not applicable	pH: Not applicable
Melting point/freezing point: Not applicable	Boiling Point: Not applicable
Flash point: Not applicable	Evaporation rate: Not applicable
Flammability (solid, gas): Not flammable	VOC: Not applicable
Flammable limits: LEL: Not applicable	UEL: Not applicable
Vapor pressure: Not applicable	Vapor density: Not applicable
Relative density: Not available	Solubility(ies): Not available
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Viscosity: Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon oxides and chlorine compounds.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of dust from damaged geltabs may cause irritation of the mucous membranes and upper respiratory tract.

Ingestion: Swallowing amounts above the recommended dosage may cause gastrointestinal effect.

Skin contact: Contact with damaged geltabs may cause slight irritation.

Eye contact: Contact with damaged geltabs may cause slight irritation with redness and tearing.

Chronic Effects: None known.

Sensitization: Components are not known to be sensitizers. Allergic reactions are possible in sensitive individuals.

Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity. In *in vitro* (Bacterial Reverse Mutation, CHO/HGPRT Forward Mutation, and Rat Lymphocyte Chromosomal Aberration assays) and *in vivo* (Mouse Bone Marrow Micronucleus assay) tests, fexofenadine hydrochloride revealed no evidence of mutagenicity.

Reproductive Toxicity: None of the components have been shown to cause reproductive toxicity. In mice, no adverse effects and no teratogenic effects during gestation were observed with fexofenadine hydrochloride at oral doses up to 3730 mg/kg. There was no evidence of teratogenicity in rats or rabbits at oral doses of terfenadine up to 300 mg/kg. In rat fertility studies, dose-related reductions in implants and increases in post-implantation losses were observed at an oral dose of 150 mg/kg of terfenadine. In mice, fexofenadine hydrochloride produced no effect on male or female fertility at average oral doses up to 4438 mg/kg.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA. No evidence of carcinogenicity was observed in an 18-month study in mice and in a 24-month study in rats at oral doses up to 150 mg/kg of terfenadine.

Acute Toxicity Values:

Fexofenadine Hydrochloride: Oral rat LD50 >5000 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values: No data is available
Persistence and degradability: No data is available
Bioaccumulative potential: No data is available
Mobility in soil: No data is available.
Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 1 Instability = 0
HMIS Rating: Health = 1 Flammability = 1 Physical Hazard = 0

SDS Revision History: New SDS.

Date of preparation: September 30, 2023

Disclaimer: This SDS 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 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 purpose(s).