



1. Product and Company Identification

PRODUCT NAME: ALLEGRA® Tablets

Substance name: Fexofenadine hydrochloride

Supplier:

Sanofi-aventis U.S. LLC
A SANOFI COMPANY
55 Corporate Drive
Bridgewater, NJ 08807

24-Hour Transport Emergency, US (Chemtrec):	(800) 424-9300
24-Hour Transport Emergency, outside US (Chemtrec):	(703) 527-3887
US Customer Service	(800) 207-8049
24-Hour Emergency, sanofi-aventis US:	(908) 981-5550

Product use: Pharmaceutical product.

2. Hazards Identification

2.1 Classification in accordance with 29 CFR 1910.1200

Classification of the finished drug product is not required according to OSHA 29 CFR 1900.1200. The following information is provided for the drug substance, fexofenadine hydrochloride:

Classification: Fexofenadine hydrochloride is not classified as a hazardous substance.

2.2 Label elements in accordance with 29 CFR 1910.1200

Labeling of the finished drug product is not required according to OSHA 29 CFR 1900.1200. The following information is provided for the drug substance, fexofenadine hydrochloride:

Signal Word: not required

Hazard Statement(s): not required

Symbol(s): not required

Precautionary Statement(s):

- Prevention: not required
- Response: not required
- Storage: not required
- Disposal: not required

2.3 Hazards Not Otherwise Classified (HNOC)

Not classified

3. Composition/Information on Ingredients

<u>Chemical Name:</u>	<u>Common Name:</u>	<u>CAS #:</u>	<u>Percentage or concentration range</u>
(±)-4-[1 hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]-butyl]- α,α -dimethyl benzeneacetic acid hydrochloride	Fexofenadine hydrochloride	153439-40-8	30, 60 or 180 mg per tablet

Inactive Ingredients: Croscarmellose sodium, magnesium stearate, microcrystalline cellulose, and pregelatinized starch. The aqueous tablet film coating is made from hypromellose, iron oxide blends, polyethylene glycol, povidone, silicone dioxide, and titanium dioxide.

4. First Aid Measures

4.1 First aid procedures

Eye contact: In case of contact with dust from broken tablets or capsules, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention.

Skin contact: In case of contact with broken tablets or capsules, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists.

Ingestion: If swallowed, call a poison center or physician immediately. Do NOT induce vomiting unless directed to do so by a physician. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water.

Inhalation: If dust from broken tablets or capsules is inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. Get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Headache, vomiting.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically and supportively.

5. Fire Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media: All means: water, carbon dioxide, foam or dry chemical.

Unsuitable extinguishing media: Strong water jet.

5.2 Specific hazards arising from the chemical

Hazardous combustion products: Carbon monoxide, carbon dioxide, oxides of nitrogen.

5.3 Special Protective Equipment and Precautions for Fire-fighters

In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. Move container from fire area if you can do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal.

6. Accidental Release Measures

6.1 Personal precautions and Protective Equipment:

Eye protection, respiratory protective equipment, and suitable protective clothing should be worn if significant dust emissions are generated from broken or crushed tablets or capsules.

6.2 Emergency Procedures:

Follow local workplace procedures. Prevent the product from entering the environment. Avoid discharges to sewers, drains, waterways, or onto the ground.

6.3 Methods for containment:

Vacuum or scoop up, moisten any dust with water before collection with a shovel or broom.

6.4 Methods for clean-up:

Place material in suitable container for disposal. Wash the floor with plenty of water, absorb or retain the cleaning water for disposal.

7. Handling and Storage

7.1 Precautions for Safe Handling

Use with adequate ventilation. Avoid breathing dust if tablets are crushed or spilled. Do not get dust in eyes or on skin. Wash thoroughly after handling.

7.2 Conditions for Safe Storage

Keep container tightly closed. Store at room temperature 20–25°C (68–77°F). Protect from light and from excessive moisture.

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Sanofi-aventis occupational exposure limit, fexofenadine hydrochloride: 0.8 mg/m³, 8-hour TWA.

8.2 Appropriate Engineering Controls

Provide adequate ventilation. No other specific controls are needed under normal handling conditions.

8.3 Individual Protection Measures

Eye/face protection: Safety glasses or safety goggles should be worn if there is a potential for dust exposure from broken or crushed tablets.

Skin protection: Suitable protective gloves should be worn if handling the unfinished product or broken or crushed tablets.

Respiratory protection: None normally required. Approved respiratory protection should be worn if there is a potential for exposure to dust from handling operations or from broken or crushed tablets.

General hygiene considerations: Suitable work clothes. Wash hands before breaks and at the end of the work shift.

9. Physical and Chemical Properties

Appearance: Peach colored tablets.

Odor: No data available.

Odor threshold: No data available.

pH: No data available.

Melting point (fexofenadine hydrochloride): 195 - 196 °C

Initial boiling point/boiling point range: Not applicable.

Flash point: Not applicable.

Evaporation rate: Not applicable.

Flammability: No data available.

Upper/lower flammability or explosive limits: Not applicable.

Vapor pressure: Not applicable.

Vapor density: Not applicable.

Relative density: No data available.

Solubility in water (fexofenadine hydrochloride): 2.44 g/l at 25 °C

Partition coefficient: n-octanol/water (fexofenadine hydrochloride): Log Kow = 0.3

Auto-ignition temperature: No data available.

Decomposition temperature (fexofenadine hydrochloride): > 400 °C

Viscosity: No data available.

10. Stability and Reactivity

10.1 Reactivity

Not a reactive material under normal handling conditions.

10.2 Chemical Stability

Stable under normal handling conditions.

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to Avoid

Keep away from heat, sparks and flames.

10.5 Incompatible materials

Strong oxidizing and reducing agents.

10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide, oxides of nitrogen.

11. Toxicological Information

The following information is for the active ingredient fexofenadine hydrochloride unless otherwise noted:

Information on likely routes of exposure: Exposure not expected under normal use. Dust from broken or crushed tablets could result in exposure to eyes, skin and respiratory tract.

Symptoms related to the physical, chemical and toxicological characteristics: Headache, vomiting.

Effects of short-term (acute) exposure: Headache, vomiting.

Effects of long-term (chronic) exposure: No data available.

Acute toxicity (LD50):

Oral route, rat: > 5,146 mg/kg

Skin corrosion/irritation: Not a skin irritant.

Serious eye damage/irritation: Slight irritant effect - does not require labelling.

Sensitization: Not a skin sensitizer.

Specific target organ toxicity – single exposure (STOT-SE): No data available.

Specific target organ toxicity – repeated exposure (STOT-RE): No data available.

Carcinogenicity: The carcinogenic potential of fexofenadine was assessed using terfenadine studies with adequate fexofenadine exposure (based on plasma area-under-the-concentration vs. time [AUC] values). 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 (which led to fexofenadine exposures that were approximately 3 and 5 times the exposure at the maximum recommended daily oral dose of fexofenadine hydrochloride in adults [180 mg] and children [60 mg] respectively).

Fexofenadine is not listed by NTP, not found to be a potential carcinogen by IARC or OSHA.

Titanium dioxide has been classified by IARC as 2B: Possibly carcinogenic to humans. Tumors were observed at high dose in animal studies by inhalation and intratracheal administration. Tumors were not observed by other routes.

Reproductive toxicity and teratogenicity: There was no evidence of teratogenicity in rats or rabbits at oral doses of terfenadine up to 300 mg/kg (which led to fexofenadine exposures that were approximately 4 and 30 times, respectively, the exposure at the maximum recommended human daily oral dose of 180 mg of fexofenadine hydrochloride in adults based on comparison of AUCs). In mice, no adverse effects and no teratogenic effects during gestation were observed with fexofenadine hydrochloride at oral doses up to 3730 mg/kg (which led to fexofenadine exposures that were approximately 15 times the exposure at the maximum recommended human daily oral dose of 180 mg of fexofenadine hydrochloride in adults based on comparison of AUCs).

In rat fertility studies, dose-related reductions in implants and increases in postimplantation losses were observed at an oral dose of 150 mg/kg of terfenadine (which led to fexofenadine exposures that were approximately 3 times the exposure at the maximum recommended human daily oral dose of 180 mg of fexofenadine hydrochloride based on comparison of AUCs). In mice, fexofenadine hydrochloride produced no effect on male or female fertility at average oral doses up to 4438 mg/kg (which led to fexofenadine exposures that were approximately 13 times the exposure at the maximum recommended human daily oral dose of 180 mg of fexofenadine hydrochloride in adults based on comparison of AUCs).

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.

Aspiration hazard: Not applicable.

12. Ecological Information

The following information is for the active ingredient fexofenadine hydrochloride unless otherwise noted:

12.1. Ecotoxicity

Fish toxicity (LC50): > 940 mg/l
Species: Lepomis macrochirus
Exposure duration: 96 h

Fish toxicity (NOEC): 570 mg/l
Species: Lepomis macrochirus
Exposure duration: 96 h

Toxicity on invertebrates (EC50): 780 mg/l
Species: Daphnia magna
Exposure duration: 48 h

Toxicity on invertebrates (NOEC): 330 mg/l
Species: Daphnia magna
Exposure duration: 48 h

Algae toxicity: > 200 mg/l
Species: Desmodesmus subspicatus
Exposure duration: 72 h
Method: OECD 201

Bacteria toxicity (EC50): > 1.000 mg/l
Species: Pseudomona fluoresc.

12.2. Persistence and degradability

Biological degradability: not readily degradable.
Testing period: 28 day

12.3. Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Other adverse effects

No data available.

13. Disposal Considerations

13.1 Disposal of product waste

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

13.2 Disposal of packaging waste

Dispose of in a safe manner in accordance with federal, state and local environmental regulations. Empty packages, containers or liners may contain product residue.

14. Transport Information

14.1 Basic shipping information, finished product

U.S. DOT	Not a regulated material.
ICAO/IATA	Not a regulated material.
IMDG	Not a regulated material.

15. Regulatory Information

US Regulations

CERCLA Hazardous Substance List (40 CFR 302.4): Not listed.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): Not listed.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): Not listed.

SARA Title III:

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): Not listed.

Section 313 Toxic Release Inventory (40 CFR 372): Not listed.

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): Titanium dioxide (airborne, unbound particles of respirable size).

Massachusetts Right-To-Know List: Titanium dioxide.

New Jersey Right-To-Know List: Titanium dioxide.

Pennsylvania Right-To-Know List: Titanium dioxide.

16. Other Information

Other Information: The information contained herein is based upon data considered true and accurate. Sanofi-aventis U.S. LLC. makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Abbreviations and Acronyms

CAS: Chemical Abstracts Service

DOT: U.S. Department of Transportation

EST: Eastern standard time (U.S.)

IATA: International Air Transport Association

IMDG: International Maritime Dangerous Goods Code

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

OEL: Occupational Exposure Limit

PPE: Personal Protection Equipment

SDS: Safety Data Sheet

STEL: Short-term exposure limit

TWA: Time-weighted average

U.S.: United States

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First version.