

**MATERIAL SAFETY DATA SHEET**

**Date of preparation: July 25, 2011**

**1. PRODUCT IDENTIFICATION**

**Product Name(s): ALLEGRA Tablets**

**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**

**2. HAZARDS IDENTIFICATION**

**Potential Health Effects**

**Eye**

As a film-coated tablet, not expected to be irritating to the eyes.

**Skin Contact**

None expected.

**Skin Absorption**

None expected.

**Ingestion**

None expected in the course of normal handling in the clinic.

**Inhalation**

As a film-coated tablet, not expected.

**Chronic Effects/Carcinogenicity**

See Section 11 for toxicology information.

**3. COMPOSITION & INFORMATION ON INGREDIENTS**

<u>Component</u>	<u>CAS#</u>
Fexofenadine hydrochloride	138452-21-8
Non-hazardous excipients	Not applicable

Product does not contain any NTP, OSHA, or IARC carcinogens.

#### **4. FIRST AID MEASURES**

##### **Eyes**

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice if irritation occurs.

##### **Skin**

If inadvertently exposed to crushed tablets, wash with soap and water. Seek medical attention if any symptoms appear.

##### **Ingestion**

If inadvertently swallowed, seek medical advice immediately and show this container or label.

##### **Inhalation**

If inadvertently exposed to crushed tablets, get fresh air. Should symptoms develop, get medical attention immediately.

##### **Note to Physician**

Additional details are available in Section 11, on the package insert or in the Physicians' Desk Reference.

#### **5. FIRE FIGHTING MEASURES**

##### **General Hazards**

In case of fire and/or explosion do not breathe fumes. CO, CO<sub>2</sub>, and oxides of nitrogen and may be generated in a fire.

##### **Fire Fighting Extinguishing Media**

In case of fire use waterspray, foam or dry chemical.

##### **Fire Fighting Instructions**

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.

##### **Hazardous Combustion Products**

CO, CO<sub>2</sub> and oxides of nitrogen and may be generated in a fire.

#### **6. ACCIDENTAL RELEASE MEASURES**

##### **Large Spill**

Scoop up, place in suitable container for disposal and mop area.

##### **Small Spill**

Same as for large spills.

#### **7. HANDLING AND STORAGE**

##### **Special Handling**

Protect product from physical damage.

##### **Special Storage**

Store at room temperature.

#### **8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

##### **Eye Protection**

For intact tablets, none required.

**Skin Protection**

For intact tablets, none required.

**Respiratory Protection**

For intact tablets, none required.

**Engineering Controls**

Manufacturing and packaging operations should be designed so as to offer no significant exposure to this material.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Physical Form:** Solid tablets.  
**Solubility in Water:** Limited

**10. STABILITY AND REACTIVITY****Incompatibility**

Heat and strong oxidizers.

**Hazardous Decomposition Products**

No data.

**Hazardous Polymerization**

Will not occur.

**General Information**

No additional information.

**11. TOXICOLOGICAL INFORMATION****Toxicology Text**

An oral LD<sub>50</sub> in rodents was not determined for fexofenadine hydrochloride as no deaths occurred, even at doses up to 5000 mg/kg. Additionally, no clinical signs of toxicity or gross pathological findings were observed. In dogs, no evidence of toxicity was observed at oral doses up to 2000 mg/kg.

Fexofenadine is an active metabolite of terfenadine and is an end product of terfenadine metabolism. The carcinogenic potential and reproductive toxicity of fexofenadine hydrochloride were assessed using terfenadine studies with adequate fexofenadine exposure (based on plasma area-under-the-curve [AUC] values). No evidence of carcinogenicity was observed when mice and rats were exposed to fexofenadine plasma AUC values four times human therapeutic value (based on 60 mg fexofenadine hydrochloride bid dose) for 18 months and 24 months, respectively. In rat reproduction and fertility studies, dose-related reductions in implants and increases in postimplantation losses were observed at fexofenadine plasma AUD values greater than or equal to three times human therapeutic value. These effects occurred at maternally toxic doses.

In vitro and in vivo fexofenadine hydrochloride mutagenicity tests showed no evidence of mutagenicity.

Teratogenic potential of fexofenadine hydrochloride was assessed using terfenadine studies with adequate fexofenadine exposure (based on plasma AUC values). There was no evidence of teratogenicity in rats or rabbits at fexofenadine plasma AUC values four times and 37 times human therapeutic value, respectively.

**12. ECOLOGICAL INFORMATION**

No information for determination of unusual environmental fate or toxicity is available at this time.

### **13. DISPOSAL CONSIDERATIONS**

#### **Disposal Information**

Waste must be disposed of in accordance with federal, state and local environmental regulations. Waste may be placed in a leakproof, puncture resistant container which is then placed in disposable wire-tie or sealable 4-mil-thick polyethylene or 2-mil-thick propylene bags.

#### **Waste Disposal Methods**

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state and local environmental regulations.

### **14. TRANSPORT INFORMATION**

Not a regulated material for transport.

### **15. REGULATORY INFORMATION**

#### **CERCLA**

Not listed.

#### **SARA Title III**

Not listed.

#### **SARA 313**

Not listed.

### **16. OTHER INFORMATION**

#### **Other Information**

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