MATERIAL SAFETY DATA SHEET

Date of preparation: January 8, 2007

1. PRODUCT IDENTIFICATION

Product Name(s): **ALLEGRA (Fexofenadine hydrochloride) Oral Suspension, 30 mg/5 mL (6 mg/mL)**

sanofi-aventis U.S.
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: **(816) 966-6300**

SECTION 2: Hazards Identification

Opaque liquid suspension with raspberry odor.

May be irritating to eyes and skin.

There is no clinical experience with an acute fexofenadine hydrochloride overdose.
Allegra is indicated for the relief of symptoms associated with seasonal allergic rhinitis.

SECTION 3: Composition/Information on Ingredients

Ingredients:	CAS #:	Occupational Exposure Limits:
Fexofenadine hydrochloride	138452-21-8	Sanofi-aventis OEL: 800 mcg/m3, 8-hour TWA
Water, purified USP	7732-18-5	ND
Propylene glycol USP	57-55-6	ND
Propylparaben, NF	94-13-3	ND
Butylparaben, NF	94-26-8	ND
Monobasic sodium phosphate monohydrate, USP	10049-21-5	ND
Dibasic sodium phosphate heptahydrate, USP	7782-85-6	ND

Poloxamer 407, NF	106392-12-5	ND
Xanthan gum, NF	11138-66-2	ND
Xylitol, NF	87-99-0	ND
Sucrose, NF	57-50-1	ACGIH 8-hour TLV 10 mg/m3
Art. Raspberry cream flavor, PFC 9950	NA	ND
Titanium dioxide, USP	13463-67-7	ACGIH 8-hour TLV 10 mg/m3

ND = Not Determined; NA = Not Available

SECTION 4: First Aid Measures

Eyes: Immediately flush eyes with water for fifteen minutes. Get medical attention.

Skin: Wash with soap and water. Get medical attention if irritation develops or persists.

There is no clinical experience with an acute fexofenadine hydrochloride overdose.

Single doses of fexofenadine hydrochloride up to 800 mg and doses up to 690 mg bid for one month were investigated without the development of clinically significant adverse events. The maximum tolerated dose of fexofenadine hydrochloride was not reached.

In the event of overdose, consider standard measures to remove any unabsorbed drug. Symptomatic and supportive treatment is recommended.

SECTION 5: Fire Fighting Measures

Extinguisher media: Carbon Dioxide, Dry Chemical Powder, Alcohol of Polymer Foam. Water may be effective for cooling.

Unusual Fire and Explosion Hazards: None.

Vapor Pressure: Not available.

Vapor Density: Not available.

Auto-ignition Temperature: Not available.

SECTION 6: Accidental Release Measures

Shovel or sweep up spill. Place in DOT approved container and seal. Dispose of in accordance with applicable federal, state and local regulations.

SECTION 7: Handling and Storage

Incompatibility: Not applicable.

SECTION 8: Exposure Controls/Personal Protection

If handling bulk liquid:

Eye protection: Saefty glasses with side shields or safety goggles.

Skin protection: Wear appropriate gloves and protective outer garments.

Ingredients listed as a carcinogen or potential carcinogen: None.
National Toxicology Program: None.
I.A.R.C. Monographs: None.
OSHA: None.

SECTION 9: Physical and Chemical Properties

Appearance: Opaque liquid suspension.
Odor: Raspberry odor.

SECTION 10: Stability and Reactivity

Material is stable under normal conditions.
Hazardous polymerization: Will not occur.

SECTION 11: Toxicological Information

An oral LD_{50} 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 post implantation 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 teratogencity in rats or rabbits at fexofenadine plasma AUC values four times and 37 times human therapeutic value, respectively.

There are no adequate and well-controlled studies in pregnant women. Fexofenadine hydrochloride should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

SECTION 12: Ecological Information

Shovel or sweep up spill. Place in DOT approved container and seal. Dispose of in accordance with applicable federal, state and local regulations

SECTION 13: Disposal Considerations

This material should be disposed of in accordance with local, state, and/or federal regulations.

SECTION 14: Transport Information

This material is not regulated as hazardous by U.S.DOT/IATA. A copy of this MSDS should accompany shipments of this material.

SECTION 15: Regulatory Information

No additional information.

SECTION 16: Other Information

The information provided in this Material Safety Data Sheet has been compiled from our experience and the data presented in various technical publications. It is the users responsibility to determine the suitability of this information for the adoption of safety precautions as may be necessary. We reserve the right to revise the Material Safety Data Sheets from time to time as new information becomes available. It is recommended that the user contact the company to make sure the sheet is the latest one issued.