Material Safety Data Sheet

PREPARATION DATE: December 30, 2002
This revision replaces the last update of March 21, 1996

SECTION 1: Chemical Product and Company Identification

Common Name: (used on the label)	TENUATE, TENUATE DOSPAN
(Trade Names & Synonyms)	diethylpropion hydrochloride
Chemical Name:	1-phenyl-2-diethylamino-1-propanone
hydrochloride	

Manufacturer:	**Aventis Pharmaceuticals, Inc.**
Address:	**Route 202-206**
	Bridgewater, NJ 08807-0800

Technical Information, M-F, 8 AM – 5 PM EST:	**(908) 231-4829**
24-Hour Transport Emergency, US (Chemtrec):	**(800) 424-9300**
24-Hour Transport Emergency, outside US (Chemtrec) :	**(703) 527-3887**
24-Hour Emergency, Aventis:	**(908) 231-2666**

SECTION 2: Composition/Information on Ingredients

Material:	TENUATE tablets, TENUATE DOSPAN tablets
	TENUATE (immediate release)-25 mg
Concentration:	TENUATE DOSPAN (controlled release)-75 mg
Nature of Hazard:	Pharmaceutical Product.

SECTION 3: Hazards Identification

Appearance :	TENUATE 25 mg-Each white, round tablet is debossed TENUATE 25 or MERRELL 697 TENUATE DOSPAN 75 mg-Each white, capsule-shaped tablet is debossed TENUATE 75 or MERRELL 698

TENUATE and TENUATE DOSPAN are indicated in the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction.

SECTION 4: First Aid Measures

Manifestation of acute overdosage include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states.
Fatigue and depression usually follow the central stimulation.
Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Castrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Overdose of pharmacologically similar compounds has resulted in convulsions, coma, and death. Management of acute diethylpropion hydrochloride intoxication is largely symptomatic and includes lavage and sedation with a barbituate. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard. Intravenous phentolamine has been suggested on pharmacologic grounds for possible acute, severe hypertension, if this complicates TENUATE or TENUATE DOSPAN overdosage.

SECTION 5: Fire Fighting Measures

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

Unusual Fire and Explosion Hazards: None.

Vapor Pressure: Not applicable.

Vapor Density: Not applicable.

Flashpoint: Not applicable.

Auto-ignition Temperature: Not applicable.

SECTION 6: Accidental Release Measures

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

SECTION 7: Handling and Storage

Incompatibility: Not applicable.
Hazardous polymerization: Will not occur.
Keep tightly closed. Store at room temperature, below 86°F.

SECTION 8: Exposure Controls/Personal Protection

OSHA Permissible Exposure Limit: Not available.

SECTION 9: Physical and Chemical Properties

Appearance: See section 3 for detailed information.

SECTION 10: Stability and Reactivity

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

SECTION 11: Toxicological Information

The reported oral LD_{50} for mice is 600 mg/kg, for rats is 250 mg/kg and for dogs is 225 mg/kg. No long-term animal studies have been done to evaluate diethylpropion hydrochloride for carcinogenicty. Mutagenicity studies have not been conducted. Animal reproduction studies have revealed no evidence of impairment of fertility.
Teratogenic Effects: Pregnancy Category B. Reproduction studies have been performed in rats at doses up to 9 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to diethylpropion hydrochloride. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human reposone, this drug should be used during pregnancy only if clearly needed. Abuse with diethylpropion hydrochloride during pregnancy may result in withdrawal symptoms in the human neonate.

SECTION 12: Ecological Information

Shovel or sweep up spill. Place in DOT approved container and seal. Dispose of in accordance with RCRA and applicable 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. 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. The user has the responsibility to contact the company to make sure the sheet is the latest one issued.