

Material Safety Data Sheet



PREPARATION DATE: 26 December 2002
This revision replaces the last update of 20 March 1996

SECTION 1: Chemical Product and Company Identification

Common Name: (used on the label)	Bentyl
(Trade Name & Synonyms)	dicyclomine hydrochloride USP
Chemical Name:	[bicyclohexyl]-1-carboxylic acid, 2-(diethylamino) ethyl ester hydrochloride
Chemical Formula:	$C_{19}H_{35}NO_2 \cdot HCl$
CAS Number:	67-92-5

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:	Bentyl
Concentration:	10 mg capsules, 20 mg tablets, 10 mg/5 ml syrup, 10 mg/ml injection
Nature of Hazard:	Pharmaceutical Product.

SECTION 3: Hazards Identification

Appearance :	10 mg blue capsules, imprinted BENTYL 10 20 mg compressed, light blue, round tablets, debossed BENTYL 20 10 mg/5 ml pink syrup 10 mg/ml injection-10 ml multiple dose vials, boxes of five 2 ml ampules
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Bentyl is a smooth muscle relaxant, prescribed for the treatment of functional bowel/irritable bowel syndrome.

SECTION 4: First Aid Measures

The signs and symptoms of overdosage are headache; nausea; vomiting; blurred vision; dilated pupils; hot, dry skin; dizziness; dryness of the mouth; difficulty in swallowing; and CNS stimulation. A curare-like action may occur (ie neuromuscular blockade leading to muscular weakness and possible paralysis).

Treatment should consist of gastric lavage, emetics, and activated charcoal. Sedatives (e.g., short-acting barbiturates, benzodiazepines) may be used for management of overt signs of excitement. If indicated, an appropriate parenteral cholinergic agent may be used as an antidote.

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: For the Bentyt Injection, there could be a broken glass hazard: Heat of fire could cause ampuls, vials, or syringes to burst.

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

Hazardous decomposition products: Burning may produce HCl and oxides of carbon and nitrogen.

Hazardous polymerization: Not applicable.

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 decomposition products: Burning may produce HCl and oxides of carbon and nitrogen.

Hazardous polymerization: Will not occur.

SECTION 11: Toxicological Information

Dicyclomine Hydrochloride-100%- Oral, mouse LD50=625 mg/kg

There are no known human data on long-term potential for carcinogenicity or mutagenicity.

Long-term studies in animals to determine carcinogenic potential are not known to have been conducted.

In studies in rats at doses of up to 100 mg/kg/day, Bentyl produced no deleterious effects on breeding, conception, or parturition.

Reproduction studies have been performed in rats and rabbits at doses up to 33 times the maximum recommended human dose based on 160 mg/day (3mg/kg) and have revealed no evidence of impaired fertility or harm to the fetus due to dicyclomine. Epidemiologic studies in pregnant women with products containing dicyclomine hydrochloride (at doses up to 40 mg/day) have not shown that dicyclomine increases the risk of fetal abnormalities if administered during the first trimester of pregnancy. There are, however, no adequate and well-controlled studies in pregnant women at the recommended doses (80-160 mg/day). Because animal reproduction studies are not always predictive of human response, Bentyl as indicated for functional bowel/irritable bowel syndrome should be used during pregnancy only if clearly needed.

SECTION 12: Ecological Information

Shovel or sweep up spill. For liquid, add absorbent. 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.