1. PRODUCT IDENTIFICATION

Trade Name: Ketek®

Aventis Pharmaceuticals, Inc.
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**

Synonyms:
Telithromycin

2. COMPOSITION / INFORMATION ON INGREDIENTS

CAS#	CHEMICAL IDENTITY	EXPOSURE LIMITS				CARCINOGEN STATUS		
		ACGIH		OSHA		IARC	NTP	OSHA
		TWA	STEL	PEL	STEL			
173838-31-8	Telithromycin	NE	NE	NE	NE	NR	NR	NR
9004-34-6	Microcrystalline Cellulose	NE	NE	NE	NE	NR	NR	NR
9005-25-8	Corn Starch	NE	NE	5 mg/m3 Respirable	NE	NR	NR	NR
63-42-3	Lactose	NE	NE	NE	NE	NR	NR	NR
557-04-0	Magnesium Stearate	10mg/m3	NE	NE	NE	NR	NR	NR
9003-39-8	Povidone K25	NE	NE	NE	NE	NR	NR	NR
	Croscarmellose Sodium							

NE = Not Established NR = Not Reviewed

3. HAZARDS IDENTIFICATION

Emergency Overview Telithromycin is a macrolide antibiotic. Macrolide antibiotics may cause sensitization by inhalation or skin contact.

Eye No data for determination of unusual hazard to the eyes is available at this time.

Skin Contact As tablets, none expected.

Skin Absorption As tablets, none expected.

Ingestion Not harmful by definition based on LD50. Adverse effects from ingestion may include nausea, vomiting, or other digestive orders. A full description of adverse side effects can be found in the package insert.

Inhalation As tablets, not expected.

Chronic Effects/ Carcinogenicity No chronic effects know. Not considered mutagenic or reprotoxic (see Section 11).

4. FIRST AID MEASURES

Eyes Not an expected route of exposure in this dosage form. In case of exposure to crushed tablets, rinse immediately with plenty of water and seek medical advice. (S26)

Skin Wash with soap and water. Seek medical attention if symptoms appear.

Ingestion In case of overdosage, seek medical attention. Induce vomiting only as directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation Not an expected route of exposure in this dosage form.

Note to Physician Telithromycin is pharmacologoically active at low doses. Allergic respiratory or cutaneous reactions have been associated with macrolide antibiotics..

5. FIRE FIGHTING MEASURES

General Hazards Combustible. CO, CO2, oxides of nitrogen compounds may be generated in a fire.

Fire Fighting Extinguishing Media In case of fire use waterspray, foam or dry chemical. (S43)

Fire Fighting Instructions Keep personnel removed from and upwind of fire. Wear full firefighting turn-out gear (full bunker gear) and self-contained breathing apparatus (SCBA).

Hazardous Combustion Products CO, CO2, and oxides of nitrogen may be generated in a fire.

6. ACCIDENTAL RELEASE MEASURES

Large Spill HEPA vacuum or scoop up and place in a suitable container for disposal. Mop and ventilate area.

Small Spill Pick up tablets. Use wetted paper towel to gather any dust.

7. HANDLING AND STORAGE

Special Handling Protect package from physical damage. Wash thoroughly after handling.

Special Storage Store according to information on the package or in the package insert.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Eye Protection Clean-up, manufacturing and packaging operations may require safety glasses or goggles if there is a potential for splashing.

Skin Protection Latex gloves or gloves of equal or greater protection are recommended for spill clean-up, manufacturing and packaging operations.

Respiratory Protection Clean-up, manufacturing and packaging operations may require respiratory protection based upon potential exposures to individual ingredients.

Engineering Controls Handle all powder forms of this compound in a properly certified fumehood to control exposure below any designated permissible exposure limit.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Tablet
Odor:	Odorless
Odor Threshold:	Not applicable
Physical State:	Solid
Solubility in Water (Telithromycin):	300 mg/L
Melting Point (Telithromycin):	176 - 188 °C
Freezing Point (Telithromycin):	Not Applicable
Bulk Density (Telithromycin):	Not determined
Octanol/water partition coefficient (Telithromycin):	Log Kow 3.53
Molecular Weight (Telithromycin):	812.02
Molecular Formula (Telithromycin):	C43 H65 N5 O10

10. STABILITY AND REACTIVITY

Incompatibility No known incompatibilities.

Hazardous Decomposition Products Thermal decomposition products may include CO, CO2, and oxides of nitrogen.

Hazardous Polymerization Hazardous polymerization has not been reported to occur under normal temperatures and pressures.

General Information No additional information.

11. TOXICOLOGICAL INFORMATION

Information is for the active ingredient, Telithromycin:

Acute Toxicity: LD50 PO Rat: Greater than 2000 mg/kg. Lethal dose, young dog, PO: greater than 1000 mg/kg.
Chronic Toxicity: Rat, dog monkey, PO: increase in hepatic enzymes and renal impairment at high doses. NOEL (rat,dog): 50 mg/kg/day. NOEL (monkey): 60 mg/kg/day. Rat: no sign of ototoxicity up to 150 mg/kg/day.
Mutagenicity: Negative in Ames, mouse lymphoma, in vivo micronucleus, and in vitro chromosomal aberration assays.
Reproductive Toxicity: No evidence of developmental or reproductive effects.
Sensitization: Not antigenic in guinea pigs.

12. ECOLOGICAL INFORMATION

Ecological Information for Telithromycin:

Very toxic to aquatic organisms (R50/53). May cause long term effects in the aquatic environment.

Biodegradability: BOD5: 24 mg/L. Biodegradability (16 days): 6%. Not readily biodegradable in natural media.

Ecotoxicity data for telithromycin:

Rainbow trout (static)	LC50, 96 hr > 308 mg/l
	NOEC, 96 hr = 308 mg/l
Daphnia (static)	EC50, 48 hr = 35.1 mg/l
	NOEC, 48 hr = 4.94 mg/l
	EC50, 24 hr > 111 mg/l

Algae (static 12 day)	Maximum standing crop:
	NOEC = 2.38 ug/l
	MIC = 5.45 ug/l
	u-max:
	NOEC = 8.21 ug/l
	MIC = 17.3 ug/l
Microbial inhibition	No inhibitory effect at 50 mg/l
Biodegradation	Not biodegradable
	10.7 % ($\pm$ 4.4%), 28 days
Hydrolysis	67% after 28 days, pH 9, 25 deg C
	Stable at pH 4, 7

13. DISPOSAL CONSIDERATIONS

Disposal Information Waste must be disposed of in accordance with federal, state and local environmental regulations. Incineration is the preferred method.

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

DOT:
Proper Shipping Name: Not Regulated
IATA:
Proper Shipping Name: Not Regulated

15. REGULATORY INFORMATION

TSCA Inventory Status: This product is a pharmaceutical agent and as such is regulated by the United States Food and Drug Administration (FDA).

16. OTHER INFORMATION

Prepared By: Stuart Dearden, CIH
Approved Date: 01/17/03

Other Information The information contained herein is based upon data considered true and accurate. Aventis Pharmaceuticals 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.

Revision Summary Original version 2/16/01.
First revision 11/15/01 (update Section 12).
Second revision 01/17/03 (update header information).