sanofi pasteur
The vaccines division of sanofi-aventis Group

Material Safety Data Sheet

Effective Date: June 7, 2006

PRODUCT AND COMPANY IDENTIFICATION

Pentacel ®
Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine

MANUFACTURED BY: Sanofi Pasteur Ltd.
Toronto Ontario Canada

DISTRIBUTED BY: Sanofi Pasteur Inc.
Swiftwater, PA

CUSTOMER SERVICE: 1-800-822-2463

HAZARD IDENTIFICATION, INCLUDING EMERGENCY OVERVIEW

HEALTH EFFECTS: Accidental injection or entry through an open wound may result in pain, redness or swelling. Persons with allergy to any component of the product could develop anaphylactic or other hypersensitivity reaction.

ENVIRONMENTAL EFFECTS: Unknown
NFPA RATINGS (SCALE 0-4): Health=0 Fire=0 Reactivity=0
For more information concerning product safety refer to the package insert, prescribing booklet or call Customer Service at the phone number listed above.

COMPOSITION / INFORMATION ON INGREDIENTS

Each dose (0.5 mL) of Pentacel® after reconstitution contains:

PURIFIED CAPSULAR POLYSACCHARIDE OF HAEMOPHILUS INFLUENZAE TYPE b	10 µg
TETANUS PROTEIN	20 µg
PERTUSSIS TOXOID (PT)	20 µg
FILAMENTOUS HAEMAGGLUTININ (FHA)	20 µg
FIMBRIAL AGGLUTINOGENS 2 +3 (FIM)	5 µg
PERTACTIN (PRN)	3 µg
DIPHTHERIA TOXOID	15 Lf
TETANUS TOXOID	5 Lf

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POLIOVIRUS TYPE 1 (Mahoney)……40 D-antigen units
POLIOVIRUS TYPE 2 (MEF-1)…… …8 D-antigen units
POLIOVIRUS TYPE 3 (Saukett)……32 D-antigen units
ALUMINUM PHOSPHATE…… 1.5 mg
2-PHENOXYETHANOL (not as preservative)…… 0.6. %
POLYSORBATE 80…….. 10 ppm (by calculation)
BOVINE SERUM……≤.50 ng
FORMALDEHYDE…… trace amounts
NEOMYCIN AND POLYMYXIN B……trace amounts

FIRST AID MEASURES

EYES: Irrigate thoroughly with water or normal saline solution for 15 – 20 minutes, occasionally lifting upper and lower lids.
Get medical attention immediately.

INHALATION: May cause irritation to nasal passages. Remove subject to fresh air.

SKIN: May cause irritation. Remove contaminated clothing.
Wash affected areas with soap and water.

INGESTION: Rinse mouth with copious amounts of water.
Get medical attention immediately.
Report all needle stick injuries.

FIREFIGHTING MEASURES

FIREFIGHTING MEDIA: Any.

FIRE FIGHTING: Move container from fire fighting area if possible.
Use agents suitable for the type of surrounding fire.
Avoid breathing vapors, keep upwind.

INCOMPATIBLE MATERIALS: Any material incompatible with water or normal saline.

ACCIDENTAL RELEASE MEASURES

SPILLAGE: Dispose of as clinical waste. Wash site of spill with a detergent solution.
Wear impervious gloves and clothing when cleaning up dust or liquid spills.

HANDLING AND STORAGE

STORAGE: Store between 2°C and 8°C (in a refrigerator). Do not freeze.

EXPOSURE CONTROLS / PERSONAL PROTECTION

Not applicable except in the case of large spills with potential for exposure during clean-up.

EXPOSURE LIMITS: Not Available
VENTILATION: Provide general dilution ventilation
RESPIRATOR: Not required **GLOVES:** Recommended
CLOTHING: No special clothing required **EYE PROTECTION:** Safety goggles
GENERAL HYGIENE: Wash contaminated skin and clothing with soap and water

PHYSICAL AND CHEMICAL PROPERTIES

DESCRIPTION: Uniform, cloudy white to off-white (yellow tinge) suspension

BOILING POINT:	Not Available	**SPECIFIC GRAVITY:**	N/A
MELTING POINT:	Not Available	**VAPOR PRESSURE:**	N/A
EVAPORATION RATE:	N/A	**ODOR THESHOLD:**	N/A
SOLUBILITY IN WATER:	>10%	**SOLVENT SOLUBILITY:**	N/A
VAPOR DENSITY:	N/A	**AUTOIGNITION TEMP:**	N/A
FIRE:	Non-flammable	**UPPER EXPLOSIVE LIMIT:**	N/A
FLASH POINT:	N/A	**LOWER EXPLOSIVE LIMIT:**	N/A

STABILITY AND REACTIVITY

REACTIVITY: Stable
INCOMPATABILITIES: Water reactive materials
DECOMPOSITION: Thermal decomposition may release small amounts of fumes
POLYMERIZATION: Not reported under normal temperatures and pressures

TOXICOLOGICAL INFORMATION

TOXICITY DATA: Not available
CARCINOGEN STATUS: Not listed by ACGIH, IARC, NIOSH, NTP, or OSHA
ACUTE TOXICITY LEVEL Non-toxic by ingestion.
TARGET EFFECTS: Nuisance dust prior to reconstitution.
AT INCREASED RISK FROM EXPOSURE: None

ECOLOGICAL INFORMATION

CERCLA RATINGS: N/A

DISPOSAL CONSIDERATIONS

Dispose of containers and contaminated spill cleanup materials as clinical waste.

TRANSPORT INFORMATION

Not subject to U.S. Transportation of Dangerous Goods Regulations

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