

SAFETY DATA SHEET

PRODUCT NAME: PNEUMOVAX™ 23**Page: 1/6****Revision 1-Apr-2010**

1. Product and Company Identification

Manufactured/Supplied by Merck Sharp & Dohme Corp.
A wholly owned subsidiary of Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ 08889-0100
(908) 423-1000 (General Information Only)

Label Name **Emergency Telephone Number:**
1-908-423-6000 (24/7/365) English Only
PNEUMOVAX™ 23

Chemical Name Pneumococcal vaccine polyvalent

Synonyms Not available

Material Product Number 4739 - One 5-dose vial of liquid vaccine.
4943 - Single-dose vial of liquid vaccine in a box of 10 single-dose vials.
NDC 0006-4739-00
NDC 0006-4943-00

Intended Use Vaccine indicated for vaccination against pneumococcal disease caused by those pneumococcal types included in the vaccine.

2. Composition/Information on Ingredients

<u>Component</u>	<u>Molecular Formula</u>	<u>Molecular weight</u>	<u>CAS Number</u>	<u>Percent (%)</u>
Pneumococcal Types 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F	Not available	Not available	Not available	<1
Inactive ingredients	---	Not available	---	99

EC Label Not classified.

3. Hazards Identification

Appearance Clear, colorless solution

Label Text CAUTION!

VACCINE

Emergency Overview No specific hazard with intact vials.

Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Potential Health Effects See Section 11 for detailed information.

*** Continued on next page ***

4. First Aid Measures

Eye Contact

None required with normal handling of finished product.

In case of contact with eyes, rinse immediately with plenty of water. Get medical attention if symptoms occur.

Skin Contact

None required with normal handling of finished product.

Wash with soap and water. Get medical attention if irritation occurs.

Inhalation

None required with normal handling of finished product.

If inhaled, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

Ingestion

None required with normal handling of finished product.

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.

Notes to physician

Treat supportively and symptomatically.

For additional guidance refer to the current prescribing information or the local poison control center.

5. Fire Fighting Measures

Flash Point

Not applicable

Flammable Limits (% in air)

Not applicable

Autoignition Temperature

Not available

Oxidizing Properties

Not available

Combustibility Information

Not available

Dust Explosivity Information

Not applicable

Shock Sensitivity

Not applicable

Fire/Explosion Hazards

None known.

Special Fire Procedures

No special procedures.

Extinguishing Media

In case of fire, use water spray (fog), foam, dry chemical, or CO₂.

Hazardous Decomposition Products

None known.

6. Accidental Release Measures

Personal Precautions

See Section 8 for Personal Protective Equipment Contact emergency personnel. Keep unnecessary personnel away. Follow all fire fighting procedures (Section 5).

Methods for cleaning up

Contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways. **See Section 13 for Waste Disposal Information**

7. Handling and StorageHandling

Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Storage

Keep container tightly closed. Store vials at 2-8°C (35.6-46.4°F)

8. Exposure Controls/Personal ProtectionExposure Guidelines

<u>Component</u>	<u>OSHA Permissible Exposure Limit (PEL)</u>	<u>ACGIH Threshold Limit Value (TLV)</u>	<u>Merck Exposure Control Limit (ECL) or PB-ECL Category</u>
Pneumococcal Types 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F	Not established	Not established	10 ug/m ³ (8-hr TWA)
Inactive ingredients	Not available	Not available	Not established

ADI = 100 ug/day

Wipe Test Criteria = 100 ug/cm²

Engineering Controls

Adequate ventilation should be provided if there is risk of aerosol formation.

Personal Protective EquipmentEye/Face Protection

None required when handling sealed vials.

Safety glasses with side shields should be worn when handling bulk liquid formulation or filling vials.

Skin Protection

None required when handling sealed vials.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Respiratory Protection

No respiratory protection required when handling bulk liquid formulation or sealed vials.

As an adjunct to engineering controls, use an approved, properly fitted, powered air purifying respirator, or respirator of equivalent or greater protection if the potential exists for exposure to airborne aerosols.

Additional Protective Equipment

Work uniform or laboratory coat.

9. Physical and Chemical Properties

<u>Appearance</u>	Clear, colorless solution
<u>Odor/Threshold Limit</u>	Not available
<u>pH</u>	Not available
<u>Boiling Point</u>	Not available
<u>Melting Point</u>	Not available
<u>Flash point</u>	Not applicable
<u>Flammable Limits (% in air)</u>	Not applicable
<u>Autoignition Temperature</u>	Not available
<u>Solubility</u>	Not available
<u>Partition Coefficient</u>	Not available
<u>Specific Gravity</u>	Not available
<u>Vapor Density</u>	Not available
<u>Vapor Pressure</u>	Not available
<u>Volatility Component</u>	Not available

10. Stability and Reactivity

<u>Stability</u>	Not available
<u>Conditions to Avoid</u>	Not available
<u>Incompatibility</u>	Not available
<u>Hazardous Polymerization</u>	Not available
<u>Hazardous Decomposition Products</u>	None known.

11. Toxicological Information

<u>Routes of Entry</u>	Ingestion:	No.
	Inhalation:	Yes
	Skin Contact:	No.

Toxicity Data

<u>Component</u>	<u>Test</u>	<u>Species</u>	<u>Route</u>	<u>Result</u>
Pneumococcal Types 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F	Not available	Not available	Not available	Not available
Inactive ingredients	Not available	Not available	Not available	Not available

Effects of Acute Exposure

<u>Eye contact</u>	Non-irritating to the eyes.
<u>Skin contact</u>	Not available
<u>Inhalation</u>	Not available
<u>Ingestion</u>	Not available

Effects of Chronic Exposure

Mutagenicity, carcinogenicity, developmental and reproductive toxicity studies have not been conducted with PNEUMOVAX 23. Repeat-dose, developmental, reproductive and genotoxicity studies have not yet been performed.

The most common adverse experiences reported in clinical trials were local reactions at the injection site (including soreness, warmth, erythema, swelling, and induration) and fever (<102°F). In postmarketing experience, injection-site cellulitis-like reactions were reported rarely. Caution and appropriate care should be exercised in administering PNEUMOVAX 23 to individuals with severely compromised cardiovascular and/or pulmonary function in whom a systemic reaction would pose a significant risk.

Carcinogen Designation

Not listed as a carcinogen by OSHA, NTP or IARC.

Medical Conditions Aggravated by Overexposure:

Not available

12. Ecological InformationEnvironmental Effects

Not available

Ecotoxicity DataComponentSpeciesPeriodResult

Pneumococcal Types
1, 2, 3, 4, 5, 6B, 7F, 8,
9N, 9V, 10A, 11A, 12F,
14, 15B, 17F, 18C, 19A,
19F, 20, 22F, 23F
Inactive ingredients

Not available

Not available

Not available

Not available

Not available

Not available

Environmental Fate

Not available

13. Disposal ConsiderationsWaste Disposal Information

Avoid contact of spilled material and runoff with soil and surface waterways. Dispose of or treat all spills residues including contaminated soils following all federal, state, or local regulations.

14. Transport InformationShipping DescriptionU.S. DOT

Not regulated.

IATA/ICAO

Not regulated.

IMO

Not regulated.

ADR/RID

Not regulated.

15. Regulatory InformationU.S. Federal Regulations

Hazardous per OSHA Hazard Communication Standard criteria (29 CFR 1910.1200).

State Regulations

Not available

International Regulations

Not classified as Dangerous according to the Dangerous Substances Directive (DSD).

16. Other Information

Revisions: Material Product Number

Revision:

4/1/2010.

Date of Preparation

10-Apr-2007

Date of Previous Issue

10-Apr-2007

Validation Date

4/1/2010.

MSDS Coordinator:

1-908-423-7903

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One Merck Drive

Whitehouse Station, NJ 08889-0100

Disclaimer:

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