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)

   **Emergency Telephone Number:**
   1-908-423-6000 (24/7/365) English Only

   **Label Name**
   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**

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

   **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).

*** Continued on next page ***
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 Storage

Handling: 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 Protection

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA Permissible Exposure Limit (PEL)</th>
<th>ACGIH Threshold Limit Value (TLV)</th>
<th>Merck Exposure Control Limit (ECL) or PB-ECL Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumococcal Types 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F</td>
<td>Not established</td>
<td>Not established</td>
<td>10 ug/m³ (8-hr TWA)</td>
</tr>
<tr>
<td>Inactive ingredients</td>
<td>Not available</td>
<td>Not available</td>
<td>Not established</td>
</tr>
</tbody>
</table>

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 Equipment

Eye/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.

*** Continued on next page ***
9. Physical and Chemical Properties

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

10. Stability and Reactivity

Stability: Not available
Conditions to Avoid: Not available
Incompatibility: Not available
Hazardous Polymerization: Not available
Hazardous Decomposition Products: None known.

11. Toxicological Information

Routes of Entry:
- Ingestion: No.
- Inhalation: Yes
- Skin Contact: No.

Toxicity Data:

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

Effects of Acute Exposure:
- Eye contact: Non-irritating to the eyes.
- Skin contact: Not available
- Inhalation: Not available
- Ingestion: Not available

*** Continued on next page ***
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 (<102ºF). 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 Information

Environmental Effects

Not available

Ecotoxicity Data

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Period</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumococcal Types</td>
<td>Not available</td>
<td>Not available</td>
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<td>1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F</td>
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<tr>
<td>Inactive ingredients</td>
<td>Not available</td>
<td>Not available</td>
<td>Not available</td>
</tr>
</tbody>
</table>

Environmental Fate

Not available

13. Disposal Considerations

Waste 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 Information

Shipping Description

<table>
<thead>
<tr>
<th>U.S. DOT</th>
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</thead>
<tbody>
<tr>
<td>IATA/ICAO</td>
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</tr>
<tr>
<td>IMO</td>
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<tr>
<td>ADR/RID</td>
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*** Continued on next page ***
15. Regulatory Information

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>State Regulations</td>
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</tr>
<tr>
<td>International Regulations</td>
<td>Not classified as Dangerous according to the Dangerous Substances Directive (DSD).</td>
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</table>

16. Other Information

Revisions: Material Product Number


Date of Preparation 10-Apr-2007

Date of Previous Issue 10-Apr-2007

Validation Date 4/1/2010.

MSDS Coordinator 1-908-423-7903

Merck Sharp & Dohme Corp.

A wholly owned subsidiary of Merck & Co., Inc.

One Merck Drive

Whitehouse Station, NJ 08889-0100

Disclaimer:

While this information and recommendations set forth are believed to be accurate as of the date hereof, MERCK & CO, INC. makes no warranty with respect hereto and disclaims all liability from reliance thereon.