1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Material Name: Prevnar 13 with 2-Phenoxyethanol

Trade Name: Prevnar 13
Synonyms: 13vPnC Multi-dose Vaccine (MDV); 13vPnC MDV; Prevnar 13 MDV
Chemical Family: Not determined
Intended Use: Pharmaceutical product

2. HAZARDS IDENTIFICATION

Appearance: White solution

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
   Short Term: In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

Known Clinical Effects: Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: swelling, tenderness, and redness at the injection site, fever, lack of appetite, irritability, sleepiness (somnolence), sleeplessness, allergic reaction, and anaphylactic reactions.


Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-PHENOXYETHANOL</td>
<td>122-99-6</td>
<td>204-589-7</td>
<td>Xi R36 Xn R22</td>
<td>1</td>
</tr>
</tbody>
</table>
MATERIAL SAFETY DATA SHEET

Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | %
Pneumococcal 13-valent Conjugate | Not Assigned | Not Listed | Not Listed | *
Aluminum phosphate | 7784-30-7 | 232-056-9 | Not Listed | *
Succinate buffer | Not assigned | Not Listed | Not Listed | *
Saline suspension | MIXTURE | Not Listed | Not Listed | *
Polysorbate 80 | 9005-65-6 | Not Listed | Not Listed | *

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
7. HANDLING AND STORAGE

General Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Storage Conditions: Store in a refrigerator.

Storage Temperature: 2 - 8 °C (35 to 45°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Aluminum phosphate
ACGIH Threshold Limit Value (TWA) 1 mg/m³

2-PHENOXYETHANOL
Austria OEL - MAKs 20 ppm
Finland OEL - TWA 110 mg/m³
Germany - TRGS 900 - TWAs 20 ppm
Germany (DFG) - MAK 110 mg/m³
Poland OEL - TWA 230 mg/m³
Slovenia OEL - TWA 20 ppm

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:

- Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
- Eyes: Wear safety glasses or goggles if eye contact is possible.
- Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
- Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solution
Molecular Formula: Mixture
Color: White
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
10. STABILITY AND REACTIVITY

Conditions to Avoid: Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Ingredients:

Acute Toxicity: (Species, Route, End Point, Dose)

Pneumococcal 13-valent Conjugate
- Rat Subcutaneous Maximum Non-Lethal Dose .5 mL
- Non-human Primate Subcutaneous Maximum Non-Lethal Dose .5 mL

Aluminum phosphate
- Mouse Oral LD 50 > 5000 mg/kg
- Rabbit Dermal LD 50 > 4640 mg/kg

Polysorbate 80
- Rat Oral LD50 25 g/kg

2-PHENOXYETHANOL
- Rat Oral LD50 1260 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

2-PHENOXYETHANOL
- Skin Irritation Rabbit Mild
- Eye Irritation Rabbit Moderate to Severe
- Skin Sensitization - GPMT Guinea Pig Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Pneumococcal 13-valent Conjugate
- 8 Week(s) Rat Subcutaneous * 0.5 mL NOAEL None identified
- 13 Week(s) Rat Subcutaneous * 0.5 mL NOAEL None identified
- 13 Week(s) Monkey Subcutaneous * 0.5 mL NOAEL None identified

Repeated Dose Toxicity Comments: Pneumococcal 13-valent Conjugate: * Notes: Doses are administrated 1 Dose/2 Weeks.

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been investigated.
13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:
Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required

Ingredients:

Aluminum phosphate
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 232-056-9

Polysorbate 80
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present

2-PHENOXYETHANOL
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 204-589-7
16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.
R36 - Irritating to eyes.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet