

## SAFETY DATA SHEET



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

<b>Material</b>	<b>INFANRIX</b>
<b>Synonym(s)</b>	<p>INFANRIX DTPa VACCINE * INFANRIX ASISI * INFANRIX DTPa AMPOLLETA * INFANRIX DTPa FERTIGSPRITZE * INFANRIX DTPa PFS * INFANRIX DTPa PREFILLED SYRINGE * INFANRIX DTPa SERINGA * INFANRIX DTPa VIAL * INFANRIX IM INJECTION * INFANRIX INJECTION * INFANRIX INJEKCE * INFANRIX INJEKTIONSVAZKA * INFANRIX JERINGA * INFANRIX MONODOSE SYRINGE * INFANRIX MONODOSE VIAL * INFANRIX PFS INTRAMUSKULARNE INJEKCIE * INFANRIX SOLUCAO INJECTAVEL * INFANRIX SOLUZIONE INIETTABILE * INFANRIX SUSPENSIJA I/M INJEKCIJAI * INFANRIX TIP-LOCK SYRINGE * INFANRIX VIAL * INFANRIX-DTPa ZAWIESINA DO INIEKCJI * NDC NO. 58160-810-11 * NDC NO. 58160-810-46 * DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE ADSORBED</p>
<b>Company Name</b>	<p>GlaxoSmithKline, Corporate Environment, Health &amp; Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response</p> <p>GlaxoSmithKline, Corporate Environment, Health &amp; Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

### 2. HAZARDS IDENTIFICATION

<b>Fire and Explosion</b>	This product is classified as non-flammable.
<b>Health</b>	<p>Handling this product in its final form presents minimal risk from occupational exposure. May produce allergic skin reactions. Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing). Health effects information is based on hazards of components.</p>
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

### \* 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
DIPHtheria Toxoid	Unassigned	Not Applicable	
FILAMENTOUS HAEMAGGLUTININ	Unassigned	Not Applicable	
NON-HAZARDOUS INGREDIENTS	Unassigned	> 99	
PERTACTIN (69 KDA OUTER MEMBRANE PROTEIN-69K)	Unassigned	Not Applicable	
PERTUSSIS TOXOID	Unassigned	Not Applicable	
TETANUS TOXOID	Unassigned	Not Applicable	

### 4. FIRST-AID MEASURES

<b>Ingestion</b>	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.
<b>Skin Contact</b>	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
<b>Eye Contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

#### NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	None.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	The components contained in this vaccine are generally not considered to cause disease in humans.
<b>Antidotes</b>	No specific antidotes are recommended.

### 5. FIRE-FIGHTING MEASURES

<b>Fire and Explosion Hazards</b>	Not expected for the product, although the packaging is combustible.
<b>Extinguishing Media</b>	Water is recommended for fires involving packaging.
<b>Special Firefighting Procedures</b>	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
<b>Hazardous Combustion Products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
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<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labelled container for recovery or disposal.
<b>Decontamination Procedures</b>	Water can be used for clean-up and decontamination operations. Sodium hypochlorite (bleach) or other strong oxidizers can be used in clean-up decontamination operations. Contaminated surfaces should be washed with water, then bleach or other oxidizing solution, followed by another water wash.

## 7. HANDLING AND STORAGE

### HANDLING

#### General Requirements

No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

### STORAGE

DO NOT FREEZE. Dispose of properly if frozen.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Other Equipment or Procedures</b>	None required for normal handling. Wash hands and arms thoroughly after handling.
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## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Appearance

#### Physical Form

Liquid suspension.

## 10. STABILITY AND REACTIVITY

<b>Stability</b>	DO NOT FREEZE - dispose of properly if frozen.
<b>Conditions to Avoid</b>	None for normal handling of this product.

## 11. TOXICOLOGY INFORMATION

### Routes of Exposure

#### Oral Toxicity

Not expected to be toxic following ingestion.

#### Inhalation Toxicity

No studies have been conducted.

#### Skin Effects

Irritation is not expected following direct contact.

#### Eye Effects

Irritation is not expected following direct contact with eyes.

### Sensitisation

Allergic skin reactions might occur following dermal exposure. Assessment based upon effects of structurally similar substances. Respiratory sensitisation (allergic) reactions might occur following exposure.

### Genetic Toxicity

Not expected to be genotoxic under occupational exposure conditions.

### Carcinogenicity

Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

### Reproductive Effects

Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

### Other Adverse Effects

None known for occupational exposure.

## 12. ECOLOGICAL INFORMATION

### Summary

No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

## 13. DISPOSAL CONSIDERATIONS

<b>Disposal Recommendations</b>	The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.
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**Regulatory Requirements** Observe all local and national regulations when disposing of this product.

## 14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

### UN Classification and Labelling

**Transport Information** Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

## 15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

### EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

### US OSHA Standard (29 CFR Part 1910.1200)

**Classification** This product is exempt from the requirements of the OSHA Hazard Communication Standard.

### Other US Regulations

**TSCA Status** Exempt

## 16. OTHER INFORMATION

**References** GSK Hazard Determination

**SDS Version Number** 16

### SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.