

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Trade name or designation of the mixture	INFANRIX-IPV
Registration number	-
Synonyms	INFANRIX POLIO * INFANRIX TETRA * INFANRIX DTPa IPV FERTIGSPRITZE * INFANRIX IPV SERINGUE PREREMPLIE * INFANRIX POLIO ENFANTS SERINGUE PREREMPLIE * DTPa-IPV * DIPHTHERIA, TETANUS, ACELLULAR PERTUSSIS ABSORBED AND INACTIVATED POLIO VIRUS VACCINE
Issue date	26-April-2013
Version number	06
Revision date	26-April-2013

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	Medicinal Product This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.
Uses advised against	No other uses are advised.

### 1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK  
980 Great West Road  
Brentford, Middlesex TW8 9GS UK  
UK General Information (normal business hours): +44-20-8047-5000  
Email Address: [msds@gsk.com](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://www.gsk.com)

### 1.4. Emergency telephone number

TRANSPORT EMERGENCIES (by country / geographic region):  
Africa / EU / Israel / Middle East  
(English / European languages): +44 (0) 1235 239 670  
Asia Pacific (except China): +65 3158 1074  
China: +86 10 5100 3039  
Middle East / Africa (Arabic-speaking countries): +44 (0) 1235 239 671  
US: +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

#### Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### 2.2. Label elements

#### Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Supplemental label information None.

2.3. Other hazards Caution - Pharmaceutical agent.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

**General information**

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
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DIPHTHERIA TOXOID	<1	Unassigned	-	-	
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**Classification:** **DSD:** -

**CLP:** -

FILAMENTOUS HAEMAGGLUTININ	<1	Unassigned	-	-	
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**Classification:** **DSD:** -

**CLP:** -

PERTACTIN	<1	Unassigned	-	-	
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**Classification:** **DSD:** -

**CLP:** -

PERTUSSIS TOXIN	<1	70323-44-3	-	-	
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**Classification:** **DSD:** T;R23/24/25

**CLP:** Acute Tox. 4;H302, Acute Tox. 3;H311, Acute Tox. 2;H330, Acute Tox. 2;H330, STOT SE 1;H370

POLIO VIRUS MAHONEY STRAIN	<1	Unassigned	-	-	
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**Classification:** **DSD:** -

**CLP:** -

POLIO VIRUS MEF-1 STRAIN	<1	Unassigned	-	-	
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**Classification:** **DSD:** -

**CLP:** -

POLIO VIRUS SAUKETT STRAIN	<1	Unassigned	-	-	
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**Classification:** **DSD:** -

**CLP:** -

TETANUS TOXOID	<1	Unassigned	-	-	
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**Classification:** **DSD:** -

**CLP:** -

Other components below reportable levels >99

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

**Composition comments**

The full text for all R- and H-phrases is displayed in section 16.

**SECTION 4: First aid measures****General information**

If you feel unwell, seek medical advice (show the label where possible). Show this safety data sheet to the doctor in attendance.

**4.1. Description of first aid measures****Inhalation**

Move to fresh air. Call a physician if symptoms develop or persist.

**Skin contact**

Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Material name: INFANRIX-IPV

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<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Get medical advice/attention if you feel unwell. Rinse mouth.
<b>4.2. Most important symptoms and effects, both acute and delayed</b>	Direct contact with eyes may cause temporary irritation.
<b>4.3. Indication of any immediate medical attention and special treatment needed</b>	Treat symptomatically.

## SECTION 5: Firefighting measures

<b>General fire hazards</b>	This product is non-flammable.
<b>5.1. Extinguishing media</b>	
<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	None known.
<b>5.2. Special hazards arising from the substance or mixture</b>	During fire, gases hazardous to health may be formed.
<b>5.3. Advice for firefighters</b>	
<b>Special protective equipment for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Special fire fighting procedures</b>	Not available.

## SECTION 6: Accidental release measures

<b>6.1. Personal precautions, protective equipment and emergency procedures</b>	
<b>For non-emergency personnel</b>	Keep unnecessary personnel away. For personal protection, see section 8.
<b>For emergency responders</b>	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.
<b>6.2. Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.
<b>6.3. Methods and material for containment and cleaning up</b>	<p>Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.</p> <p>Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.</p> <p>Never return spills in original containers for re-use.</p>
<b>6.4. Reference to other sections</b>	For personal protection, see section 8. For waste disposal, see section 13.

## SECTION 7: Handling and storage

<b>7.1. Precautions for safe handling</b>	Use care in handling/storage.
<b>7.2. Conditions for safe storage, including any incompatibilities</b>	Store in accordance with local/regional/national/international regulation. Store away from incompatible materials (see Section 10 of the MSDS).
<b>7.3. Specific end use(s)</b>	Medicinal Product

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Occupational exposure limits

<b>GSK Components</b>	<b>Type</b>	<b>Value</b>	<b>Note</b>
PERTUSSIS TOXIN (CAS 70323-44-3)	OHC	5	PROVISIONAL
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).		
<b>Recommended monitoring procedures</b>	Follow standard monitoring procedures.		
<b>Derived No Effect Level (DNEL)</b>	Not available.		

<b>Predicted no effect concentrations (PNECs)</b>	Not available.
<b>8.2. Exposure controls</b>	
<b>Appropriate engineering controls</b>	General ventilation normally adequate.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>General information</b>	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)
<b>Skin protection</b>	
- <b>Hand protection</b>	For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- <b>Other</b>	Not normally needed.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>Hygiene measures</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.
<b>Environmental exposure controls</b>	
<b>Hazard guidance and control recommendations</b>	Not available.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Appearance

<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not applicable.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not applicable.
<b>Evaporation rate</b>	Not applicable.
<b>Flammability (solid, gas)</b>	Not applicable.

#### Upper/lower flammability or explosive limits

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not applicable.
<b>Vapour density</b>	Not applicable.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not applicable.
<b>Explosive properties</b>	Not available.
<b>Oxidizing properties</b>	Not available.
<b>9.2. Other information</b>	No relevant additional information available.

## SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	None known.
10.6. Hazardous decomposition products	No hazardous decomposition products are known.

## SECTION 11: Toxicological information

General information	Caution - Pharmaceutical agent.
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### Information on likely routes of exposure

Ingestion	Health injuries are not known or expected under normal use.
Inhalation	Not available.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Symptoms	Not established.

### 11.1. Information on toxicological effects

Acute toxicity	None known.
Skin corrosion/irritation	Health injuries are not known or expected under normal use.
Serious eye damage/eye irritation	None known. Health injuries are not known or expected under normal use.
Respiratory sensitisation	Not available.
Skin sensitisation	Not available.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Reproductive toxicity	Contains no ingredient listed as toxic to reproduction
Specific target organ toxicity - single exposure	None known.
Specific target organ toxicity - repeated exposure	None known.
Aspiration hazard	Due to lack of data the classification is not possible.
Mixture versus substance information	Not available.
Other information	The following adverse effects have been noted with therapeutic use of this material: restlessness; irritability; headache; nausea; vomiting; diarrhoea; somnolence

## SECTION 12: Ecological information

12.1. Toxicity	Not expected to be harmful to aquatic organisms.
12.2. Persistence and degradability	No data is available on the degradability of this product.
12.3. Bioaccumulative potential	No data available for this product.
Partition coefficient n-octanol/water (log Kow)	Not available.
Bioconcentration factor (BCF)	Not available.
12.4. Mobility in soil	Not available.
12.5. Results of PBT and vPvB assessment	Not available.
12.6. Other adverse effects	Not available.
12.7. Additional information	None known.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

<b>Residual waste</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal.
<b>EU waste code</b>	Not available.
<b>Disposal methods/information</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.

## SECTION 14: Transport information

<b>ADR</b>	Not regulated as dangerous goods.
<b>RID</b>	Not regulated as dangerous goods.
<b>ADN</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### EU regulations

<b>Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I</b>	Not listed.
<b>Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II</b>	Not listed.
<b>Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended</b>	Not listed.
<b>Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended</b>	Not listed.
<b>Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended</b>	Not listed.
<b>Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended</b>	Not listed.
<b>Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended</b>	Not listed.
<b>Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry</b>	Not listed.
<b>Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA</b>	Not listed.

#### Authorisations

<b>Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended</b>	Not listed.
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#### Restrictions on use

<b>Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended</b>	Not listed.
<b>Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work</b>	Not listed.
<b>Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding</b>	Not listed.

#### Other EU regulations

<b>Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances</b>	Not listed.
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**Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.**

Always applicable.

**Directive 94/33/EC on the protection of young people at work**

Not regulated.

**Other regulations**

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

**National regulations**

Not available.

**15.2. Chemical safety assessment**

No Chemical Safety Assessment has been carried out.

**SECTION 16: Other information**

**List of abbreviations**

Not available.

**References**

GSK Hazard Determination

**Information on evaluation method leading to the classification of mixture**

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

**Full text of any statements or R-phrases and H-statements under Sections 2 to 15**

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.  
H302 Harmful if swallowed.  
H311 Toxic in contact with skin.  
H330 Fatal if inhaled.  
H370 Causes damage to organs.

**Revision information**

Product and Company Identification: Business Units  
Composition / Information on Ingredients: Ingredients  
Physical & Chemical Properties:  
TRANSPORT INFORMATION:

**Training information**

Follow training instructions when handling this material.

**Disclaimer**

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.