

## 1. Identification

### Product identifier

**INFANRIX HEXA**

### Other means of identification

#### Synonyms

DTPa-HepB-IPV/Hib \* INFANRIX-HepB-IPV/Hib \* INFANRIX Hexa INIETTABILE \* INFANRIX Hexa INJECTABLE \* INFANRIX Hexa INJECTION \* INFANRIX Hexa INJEKTIONSVATSKA \* INFANRIX Hexa JERINGA PRELLENADA \* INFANRIX-Hexa JERINGA PRE-LLENADA MONODOSIS \* DIPHTHERIA, TETANUS, ACELLULAR PERTUSSIS, HEPATITIS B (RECOMBINANT), INACTIVATED POLIO VIRUS AND HAEMOPHILUS INFLUENZA TYPE B CONJUGATE VACCINE

### Recommended use

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.

### Recommended restrictions

No other uses are advised.

### Manufacturer/Importer/Supplier/Distributor information

#### Manufacturer

GlaxoSmithKline US  
5 Moore Drive  
Research Triangle Park, NC 27709 USA  
US General Information (normal business hours): +1-888-825-5249  
Email Address: [msds@gsk.com](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://www.gsk.com)  
EMERGENCY PHONE NUMBERS -  
TRANSPORT EMERGENCIES::  
US / International toll call +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

### Classified hazards

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

### Label elements

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

### Hazard(s) not otherwise classified (HNOC)

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

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
DIPHTHERIA TOXOID		Unassigned	<1
FILAMENTOUS HAEMAGGLUTININ		Unassigned	<1
HAEMOPHILUS INFLUENZAE TYPE b CAPSULAR POLYSACCHARIDE		Unassigned	<1
HEPATITIS B VIRUS SURFACE ANTIGEN		Unassigned	<1
INACTIVATED POLIO VIRUS TYPE 1		Unassigned	<1
INACTIVATED POLIO VIRUS TYPE 2		Unassigned	<1

Chemical name	Common name and synonyms	CAS number	%
INACTIVATED POLIO VIRUS TYPE 3		Unassigned	<1
PERTACTIN		Unassigned	<1
PERTUSSIS TOXOID	HISTAMINE-SENSITIZING FACTOR * IAP * ISLET ACTIVATING PROTEIN * LYMPHOCYTOSIS-PROMOTING FACTOR	Unassigned	<1
TETANUS TOXOID		Unassigned	<1
Other components below reportable levels			90

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

#### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist. If breathing is difficult, trained personnel should give oxygen. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). Get medical attention if symptoms occur. Do not induce vomiting without advice from poison control center.
<b>Most important symptoms/effects, acute and delayed</b>	None known.
<b>Indication of immediate medical attention and special treatment needed</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Foam. Dry chemical powder. Carbon dioxide (CO2). Water.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire-fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	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. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.  Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.
<b>Environmental precautions</b>	Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid prolonged exposure. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

GSK Components	Type	Value	Note
PERTUSSIS TOXOID (CAS Unassigned)	OHC	5	PROVISIONAL

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls** An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. General ventilation normally adequate.

### Individual protection measures, such as personal protective equipment

**Eye/face protection** Not normally needed. If contact is likely, safety glasses with side shields are recommended.

**Hand protection** Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

**Skin protection**

**Other** Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

**Respiratory protection** No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations** 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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Liquid.
<b>Form</b>	Vial.
<b>Color</b>	Not available.

**Odor** Not available.

**Odor threshold** Not available.

**pH** Not available.

**Melting point/freezing point** Not available.

**Initial boiling point and boiling range** Not available.

**Flash point** Not available.

**Evaporation rate** Not available.

**Flammability (solid, gas)** Not available.

### Upper/lower flammability or explosive limits

**Flammability limit - lower (%)** Not available.

**Flammability limit - upper (%)** Not available.

**Explosive limit - lower (%)** Not available.

**Explosive limit - upper (%)** Not available.

**Vapor pressure** Not available.

**Vapor density** Not available.

**Relative density** Not available.

<b>Solubility(ies)</b>	
<b>Solubility (water)</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 available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.
<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use.
<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	None known.

### Information on toxicological effects

<b>Acute toxicity</b>	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.
<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use.
<b>Serious eye damage/eye irritation</b>	Health injuries are not known or expected under normal use.
<b>Respiratory or skin sensitization</b>	
<b>Respiratory sensitization</b>	Not available.
<b>Skin sensitization</b>	None known. This product is not expected to cause skin sensitization.
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
<b>Carcinogenicity</b>	Not classifiable as to carcinogenicity to humans.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

	Not listed.
<b>Reproductive toxicity</b>	Contains no ingredient listed as toxic to reproduction
<b>Specific target organ toxicity - single exposure</b>	Not assigned.
<b>Specific target organ toxicity - repeated exposure</b>	None known.
<b>Aspiration hazard</b>	Not likely, due to the form of the product.
<b>Further information</b>	Caution - Pharmaceutical agent.

## 12. Ecological information

<b>Ecotoxicity</b>	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	No data available.

**Mobility in soil** No data available.

**Other adverse effects** Not available.

### 13. Disposal considerations

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products** 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).

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

#### DOT

Not regulated as a dangerous good.

#### IATA

Not regulated as dangerous goods.

#### IMDG

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** 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.

### 15. Regulatory information

**US federal regulations** One or more components are not listed on TSCA.

#### **TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

#### **CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

#### **SARA 304 Emergency release notification**

Not regulated.

#### **OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

#### **Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories** Immediate Hazard - Yes  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

#### **SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** No

#### **SARA 313 (TRI reporting)**

Not regulated.

#### **Other federal regulations**

##### **Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

##### **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

## US state regulations

### US. Massachusetts RTK - Substance List

Not regulated.

### US. New Jersey Worker and Community Right-to-Know Act

Not listed.

### US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

### US. Rhode Island RTK

Not regulated.

### US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

## International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

Issue date	08-14-2014
Revision date	08-14-2014
Version #	15
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 1 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 1 Flammability: 0 Instability: 0
References	GSK Hazard Determination
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.
Revision Information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: Transport Information: Regulatory Information: United States GHS: Classification