



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>ENGERIX-B</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	ENGERIX B ADULT INJECTION 20 MCG/ML * ENGERIX B 20mcg ADULT * ENGERIX B (ADULT) * ENGERIX-B ADULT VACCINE * ENGERIX B ADULTOS * ENGERIX B ZA ODRASLE * ENGERIX®-B ERWACHSENE * ENGERIX®-B KINDER * ENGERIX B 20 * ENGERIX B INJECTABLE SUSPENSION * ENGERIX B SUSPENSIÓN INYECTABLE * ENGERIX B VACUNA CONTRA LA HEPATITIS B RECOMBINANTE 20MCG/ML * ENGERIX B PAEDIATRIC INJECTION 10 MCG/0.5 ML * ENGERIX B 10 MCG * ENGERIX B PAEDIATRIC * ENGERIX B JUNIOR * ENGERIX-B HEPATITIS B SURFACE ANTIGEN RECOMBINANT (YEAST) 20 MICROGRAM/1ML INJECTION SYRINGE * ENGERIX-B PAEDIATRIC DOSE HEPATITIS B SURFACE ANTIGEN RECOMBINANT (YEAST) 10 MICROGRAM/0.5ML INJECTION SYRINGE (ANZ) * ENGERIX-B PAEDIATRIC DOSE HEPATITIS B SURFACE ANTIGEN RECOMBINANT (YEAST) 10 MICROGRAM/0.5ML INJECTION VIAL (ANZ) * ENGERIX-B SUSPENSION FOR INJECTION, 10 MCG/0.5ML, PAEDIATRIC (PRESCRIPTION) (ANZ) * ENGERIX-B VACCINE SUSPENSION FOR INJECTION, 20 MCG/ML, ADULT (PRESCRIPTION) (ANZ) * HEPATITIS B SURFACE ANTIGEN VACCINE * HEPATITIS B (RECOMBINANT DNA) VACCINE (ADSORBED)
<b>Recommended use</b>	Not available.
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	

<b>COMPANY NAME</b>	GlaxoSmithKline US
<b>Address:</b>	5 Moore Drive Research Triangle Park, NC 27709 USA
<b>Telephone:</b>	+1-888-825-5249 (General Inquiries)
<b>Email:</b>	msds@gsk.com
<b>Website:</b>	www.gsk.com

## EMERGENCY CONTACTS

<b>Telephone:</b>	VERISK 3E GLOBAL INCIDENT RESPONSE +(1) 760 476 3971 (In country) +(1) 760 476 3962 or +(1) 866 519 4752 (International) 24/7; multi-language response
<b>Contract Number:</b>	334878

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>Environmental hazards</b>	Not classified.
<b>OSHA defined hazards</b>	Not classified.
<b>Label elements</b>	
<b>Hazard symbol</b>	None.
<b>Signal word</b>	None.
<b>Hazard statement</b>	The mixture does not meet the criteria for classification.
<b>Precautionary statement</b>	
<b>Prevention</b>	Not available.
<b>Response</b>	Not available.
<b>Storage</b>	Not available.
<b>Disposal</b>	Not available.

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

This product is non-flammable.  
 Caution - Pharmaceutical agent. See section 11 of the SDS for additional information on health hazards.

**Supplemental information**

3% of the mixture consists of component(s) of unknown acute oral toxicity. 3% of the mixture consists of component(s) of unknown acute dermal toxicity. 3% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 3% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

**3. Composition/information on ingredients****Mixtures**

Chemical name	Common name and synonyms	CAS number	%
ALUMINIUM HYDROXIDE	ALUMIGEL ALUMINA HYDRATED ALUMINA TRIHYDRATE ALPHA-ALUMINA TRIHYDRATE ALUMINIC ACID ALUMINIUM HYDROXIDE ALUMINUM HYDRATE ALUMINUM(III) HYDROXIDE ALUMINUM HYDROXIDE GEL ALUMINUM OXIDE TRIHYDRATE ALUMINUM TRIHYDRATE ALUMINUM TRIHYDROXIDE	21645-51-2	≤ 1
DISODIUM HYDROGEN PHOSPHATE	DISODIUM HYDROGEN ORTHOPHOSPHATE PHOSPHORIC ACID, DISODIUM SALT DIBASIC SODIUM PHOSPHATE DISODIUM MONOHYDROGEN PHOSPHATE DSP EXSICCATED SODIUM PHOSPHATE SODA PHOSPHATE DISODIUM PHOSPHORIC ACID SODIUM MONOHYDROGEN PHOSPHATE DISODIUM ACID ORTHOPHOSPHATE DISODIUM HYDROPHOSPHATE HYDROGEN DISODIUM PHOSPHATE DISODIUM HYDROGEN PHOSPHATE ANHYDROUS SODIUM PHOSPHATE DIBASIC DISODIUM PHOSPHATE TRISODIUM PHOSPHATE	7558-79-4	≤ 1
THIOMERSAL	MERCURATE(1-), ETHYL(2-MERCAPTOBENZOATE(2-)-O, S)-, SODIUM MERCURY, ETHYL(HYDROGEN O-MERCAPTOBENZOATO)-, SODIUM SALT ETHYLMERCURITHIOSALICYLIC ACID, SODIUM SALT SODIUM ETHYLMERCURITHIOSALICYLATE MERCUROTHIOLATE MERTHIOLATE SODIUM THIMEROSAL	54-64-8	≤ 0.1
Other components below reportable levels			>96

**4. First-aid measures****Inhalation**

Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

**Skin contact**

Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if irritation develops and persists.

**Eye contact**

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Get medical attention if irritation develops and persists.

<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
<b>Most important symptoms/effects, acute and delayed</b>	Direct contact with eyes may cause temporary irritation.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically. 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>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<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>	This material is non-flammable.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. 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. Absorb in vermiculite, dry sand or earth and place into containers. 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.  Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	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>	Storage temperature: between 2 and 8 °C (36 to 46 °F). Do not freeze. Dispose of properly if frozen. Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

<b>GSK Components</b>	<b>Type</b>	<b>Value</b>
DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)	8 HR TWA	5000 mcg/m <sup>3</sup>
	OHC	1

**US. OSHA Table Z-2 (29 CFR 1910.1000)**

Components	Type	Value
THIOMERSAL (CAS 54-64-8)	Ceiling	0.04 mg/m <sup>3</sup>
	TWA	0.01 mg/m <sup>3</sup>

**US. OSHA Table Z-3 (29 CFR 1910.1000)**

Components	Type	Value	Form
ALUMINIUM HYDROXIDE (CAS 21645-51-2)	TWA	5 mg/m <sup>3</sup>	Respirable fraction.
		15 mg/m <sup>3</sup>	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

**US. ACGIH Threshold Limit Values**

Components	Type	Value	Form
ALUMINIUM HYDROXIDE (CAS 21645-51-2)	TWA	1 mg/m <sup>3</sup>	Respirable fraction.
THIOMERSAL (CAS 54-64-8)	STEL	0.03 mg/m <sup>3</sup>	
	TWA	0.01 mg/m <sup>3</sup>	

**US. NIOSH: Pocket Guide to Chemical Hazards**

Components	Type	Value
THIOMERSAL (CAS 54-64-8)	STEL	0.03 mg/m <sup>3</sup>
	TWA	0.01 mg/m <sup>3</sup>

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

**Exposure guidelines****US - California OELs: Skin designation**

THIOMERSAL (CAS 54-64-8) Can be absorbed through the skin.

**US - Tennessee OELs: Skin designation**

THIOMERSAL (CAS 54-64-8) Can be absorbed through the skin.

**US ACGIH Threshold Limit Values: Skin designation**

THIOMERSAL (CAS 54-64-8) Danger of cutaneous absorption

**US NIOSH Pocket Guide to Chemical Hazards: Skin designation**

THIOMERSAL (CAS 54-64-8) Can be absorbed through the skin.

**Appropriate engineering controls**

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.

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

**Eye/face protection** Not normally needed. Wear safety glasses with side shields (or goggles).

**Skin protection**

**Hand protection** Not normally needed. Wear appropriate chemical resistant gloves.

**Other** Not normally needed. Wear suitable protective clothing.

**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>	Suspension. Vial. Pre-filled syringe.
<b>Color</b>	Turbid. White.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	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.
<b>Other information</b>	
<b>Explosive properties</b>	Not established.
<b>Oxidizing properties</b>	Not established.

## 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. DO NOT FREEZE - dispose of properly if frozen.
<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>	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Health injuries are not known or expected under normal use. Prolonged inhalation may be harmful.
<b>Skin contact</b>	No adverse effects due to skin contact are expected.
<b>Eye contact</b>	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	Health injuries are not known or expected under normal use.

**Symptoms related to the physical, chemical and toxicological characteristics** Direct contact with eyes may cause temporary irritation.

**Information on toxicological effects**

**Acute toxicity** Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
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DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)

**Acute**

**Oral**

LD50	Rat	17 g/kg
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**Skin corrosion/irritation** Health injuries are not known or expected under normal use.

**Serious eye damage/eye irritation** Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

**Respiratory or skin sensitization**

**Respiratory sensitization** Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

**Skin sensitization** This product is not expected to cause skin sensitization.

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. Health injuries are not known or expected under normal use.

**Carcinogenicity** Carcinogenic effects are not expected as a result of occupational exposure. Not classifiable as to carcinogenicity to humans.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity** This product is not expected to cause reproductive or developmental effects.

**Specific target organ toxicity - single exposure** Not assigned. Based on available data, the classification criteria are not met.

**Specific target organ toxicity - repeated exposure** Not assigned. Based on available data, the classification criteria are not met.

**Aspiration hazard** Not established.

**Chronic effects** Prolonged inhalation may be harmful.

**Further information** Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

**12. Ecological information**

**Ecotoxicity** 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.

Components	Species	Test Results
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ALUMINIUM HYDROXIDE (CAS 21645-51-2)

**Aquatic**

*Acute*

Algae	NOEC	Green algae (Selenastrum capricornutum)	> 100 mg/l, 72 hours
Crustacea	NOEC	Water flea (Daphnia magna)	> 100 mg/l, 48 hours
Fish	NOEC	Brown trout (Adult Salmo trutta)	> 100 mg/l, 96 hours Static renewal test

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)

**Aquatic**

*Acute*

Crustacea	EC50	Water flea (Daphnia magna)	252 mg/l
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**Persistence and degradability** No data is available on the degradability of any ingredients in the mixture.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

**Mobility in general**

**Other adverse effects** Not available.

### 13. Disposal considerations

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

**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). Avoid discharge into water courses or onto the ground.

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

### 14. Transport information

#### DOT

Not regulated as a dangerous good.

Read safety instructions, SDS and emergency procedures before handling. Not available.

#### 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** Not applicable.

### 15. Regulatory information

**US federal regulations** This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

#### Toxic Substances Control Act (TSCA)

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

Not regulated.

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

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4) Listed.

#### SARA 304 Emergency release notification

Not regulated.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

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

##### 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

THIOMERSAL (CAS 54-64-8)

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

Not regulated.

**Safe Drinking Water Act (SDWA)** Contains component(s) regulated under the Safe Drinking Water Act.

## US state regulations

### California Proposition 65



**WARNING:** 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. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

### California Proposition 65 - CRT: Listed date/Developmental toxin

THIOMERSAL (CAS 54-64-8)

Listed: July 1, 1990

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

**Issue date** 05-29-2018

**Revision date** 12-15-2021

**Version #** 19

**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** This document has undergone significant changes and should be reviewed in its entirety.