

1. Identification

Product identifier	ENGERIX-B
Other means of identification	
Synonyms	ENGERIX B ADULT INJECTION 20 MCG/ML * ENGERIX B PAEDIATRIC INJECTION 10 MCG/0.5 ML * HEPATITIS B SURFACE ANTIGEN VACCINE * HEPATITIS B (RECOMBINANT DNA) VACCINE (ADSORBED)
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
Website: 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	%
ALUMINIUM HYDROXIDE	AF 260 * ALCOA 331 * ALCOA C 30BF * 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 * ALUSAL * AMBEROL ST 140F * AMPHOJEL * BACO AF 260 * BRITISH ALUMINUM AF 260 * C 31 * C 33 * C 31C * C 4D * C 31F * C-31-F * C.I. 77002 * GHA 331 * GHA 332 * H 46 * HIGILITE * HIGILITE H 32 * HIGILITE H 42 * HIGILITE H 31S * HYCHOL 705 * HYDRAL 705 * HYDRAL 710 * HYDRATED ALUMINA * LIQUIGEL * MARTINAL * P 30BF * PGA * TRIHYDRATED ALUMINA * TRIHYDROXYALUMINUM	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
HEPATITIS B VIRUS SURFACE ANTIGEN		Unassigned	<1
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT	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

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

4. First-aid measures

Inhalation	If not breathing, give artificial respiration. If breathing is difficult, trained personnel should give oxygen. Get medical attention immediately.
Skin contact	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention if symptoms occur.
Eye contact	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth thoroughly. Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
Most important symptoms/effects, acute and delayed	None known.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. IF exposed or concerned: Get medical advice/attention.

5. Fire-fighting measures

Suitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire-fighting equipment/instructions

Move containers from fire area if you can do so without risk.

General fire hazards

This product is expected to be non-combustible.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

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.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills in original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

Environmental precautions

7. Handling and storage

Precautions for safe handling

Avoid prolonged exposure. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

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
DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)	8 HR TWA	5000 mcg/m3
	OHC	1

US. OSHA Table Z-2 (29 CFR 1910.1000) Components	Type	Value
ETHYLMERCURITHIOSALI CYLIC ACID SODIUM SALT (CAS 54-64-8)	Ceiling	0.04 mg/m3
	TWA	0.01 mg/m3

US. ACGIH Threshold Limit Values Components	Type	Value	Form
ALUMINIUM HYDROXIDE (CAS 21645-51-2)	TWA	1 mg/m3	Respirable fraction.
ETHYLMERCURITHIOSALI CYLIC ACID SODIUM SALT (CAS 54-64-8)	STEL	0.03 mg/m3	
	TWA	0.01 mg/m3	

US. NIOSH: Pocket Guide to Chemical Hazards**Components** **Type****Value**

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)	STEL	0.03 mg/m ³
	TWA	0.01 mg/m ³

Biological limit values**ACGIH Biological Exposure Indices****Components** **Value****Determinant****Specimen****Sampling Time**

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)	120 µg/g	Total inorganic mercury	Creatinine in urine	*
---	----------	-------------------------	---------------------	---

* - For sampling details, please see the source document.

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

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8) Can be absorbed through the skin.

US - Tennessee OELs: Skin designation

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8) Can be absorbed through the skin.

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8) Can be absorbed through the skin.

Appropriate engineering controls

No special ventilation requirements.

Individual protection measures, such as personal protective equipment**Eye/face protection**

Wear safety glasses with side shields.

Hand protection

Not normally needed.

Other

No special protective equipment required.

Respiratory protection

No personal respiratory protective equipment normally required.

Thermal hazards

Not available.

General hygiene considerations

Wash hands before breaks and immediately after handling the product.

9. Physical and chemical properties**Appearance****Physical state**

Liquid.

Form

Vaccine.

Color

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.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Not established. Expected to be a low ingestion hazard.
Inhalation	Not established.
Skin contact	Not established.
Eye contact	Not established. Direct contact with eyes may cause temporary irritation.
Symptoms related to the physical, chemical and toxicological characteristics	None known.

Information on toxicological effects

Acute toxicity	Due to lack of data the classification is not possible. Health injuries are not known or expected under normal use.
-----------------------	---

Components	Species	Test Results
DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)		
Acute		
Oral		
LD50	Rat	17 g/kg
* Estimates for product may be based on additional component data not shown.		
Skin corrosion/irritation	Due to lack of data the classification is not possible. Health injuries are not known or expected under normal use.	
Serious eye damage/eye irritation	Due to lack of data the classification is not possible. Health injuries are not known or expected under normal use.	
Respiratory or skin sensitization	Due to lack of data the classification is not possible.	
Respiratory sensitization	Due to lack of data the classification is not possible.	
Skin sensitization	Due to lack of data the classification is not possible.	
Germ cell mutagenicity	Due to lack of data the classification is not possible. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	

Carcinogenicity Due to lack of data the classification is not possible. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Due to lack of data the classification is not possible.

Specific target organ toxicity - single exposure Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure Due to lack of data the classification is not possible.

Aspiration hazard Not available.

12. Ecological information

Ecotoxicity Contains a substance which causes risk of hazardous effects to the environment.

Components	Species	Test Results
ALUMINIUM HYDROXIDE (CAS 21645-51-2)		
Aquatic		
<i>Acute</i>		
Algae	NOEC	Green algae (<i>Selenastrum capricornutum</i>)
Crustacea	NOEC	Water flea (<i>Daphnia magna</i>)
Fish	NOEC	Brown trout (Adult <i>Salmo trutta</i>)
DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)		
Aquatic		
<i>Acute</i>		
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)
		252 mg/l

* Estimates for product may be based on additional component data not shown.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential 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

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 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

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

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (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)

US state regulations

US. Massachusetts RTK - Substance List

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

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

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

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

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

US. Rhode Island RTK

DISODIUM HYDROGEN PHOSPHATE (CAS 7558-79-4)
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

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

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8) Listed: July 1, 1990

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

Country(s) or region	Inventory name	On inventory (yes/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	08-08-2014
Revision date	08-08-2014
Version #	17
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	Composition / Information on Ingredients: Ingredients First-aid measures: Most important symptoms/effects, acute and delayed Fire-fighting measures: Unsuitable extinguishing media Fire-fighting measures: Specific methods Physical & Chemical Properties: Multiple Properties Physical and chemical properties: <INDENT>Form Regulatory Information: United States Other information, including date of preparation or last revision: References Other information, including date of preparation or last revision: Further information