

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Trade name or designation of the mixture ENGERIX-B

Registration number -

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)

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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
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +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 Not applicable.

2.3. Other hazards

This product is expected to be non-combustible.
Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients**3.2. Mixtures**

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
ALUMINIUM HYDROXIDE	1	21645-51-2 244-492-7	-	-	
Classification:	DSD: -				
	CLP: -				
DISODIUM HYDROGEN PHOSPHATE	1	7558-79-4 231-448-7	-	-	
Classification:	DSD: -				
	CLP: -				
HEPATITIS B VIRUS SURFACE ANTIGEN	<1	Unassigned -	-	-	
Classification:	DSD: -				
	CLP: -				
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT	0.1	54-64-8 200-210-4	-	080-004-00-7	
Classification:	DSD: T+;R26/27/28, R33, N;R50/53				A,1
	CLP: Acute Tox. 2;H300, Acute Tox. 1;H310, STOT RE 2;H373, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				1,A

Other components below reportable levels >96

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 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.

4.1. Description of 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 centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms and effects, both acute and delayed None known.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

SECTION 5: Firefighting measures

General fire hazards This product is expected to be non-combustible.

5.1. Extinguishing media

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters

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

Special fire fighting procedures

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

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.

For emergency responders

Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material 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.

6.4. Reference to other sections

For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid prolonged exposure. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

7.3. Specific end use(s)

Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components

Type

Value

DISODIUM HYDROGEN
PHOSPHATE (CAS
7558-79-4)

8 HR TWA

5000 mcg/m3

OHC

1

Ireland. Occupational Exposure Limits Components

Type

Value

ETHYLMERCURITHIOSALI
CYLIC ACID SODIUM SALT
(CAS 54-64-8)

STEL

0.03 mg/m3

TWA

0.01 mg/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures

Not available.

Derived no-effect level (DNEL)

Not available.

Predicted no effect concentrations (PNECs)

Not available.

Exposure guidelines

Ireland Exposure Limit Values: Skin designation

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

8.2. Exposure controls

Appropriate engineering controls

No special ventilation requirements.

Individual protection measures, such as personal protective equipment

General information	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eye/face protection	Wear safety glasses with side shields. (eg. EN 166)
Skin protection	
- Hand protection	Not normally needed.
- Other	No special protective equipment required.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Not available.
Hygiene measures	Wash hands before breaks and immediately after handling the product.
Environmental exposure controls	
Hazard guidance and control recommendations	Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Liquid.
Form	Vaccine.
Colour	Not available.
Odour	Not available.
Odour 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.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Solubility (other)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.

9.2. Other information

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	Strong oxidising agents.

10.6. Hazardous decomposition products

Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information Health injuries are not known or expected under normal use.

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 None known.

11.1. 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		
<i>Oral</i>		
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 sensitisation Due to lack of data the classification is not possible.

Skin sensitisation 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.

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.

Mixture versus substance information Not available.

Other information Not available.

SECTION 12: Ecological information

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

Components		Species	Test results
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

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

12.2. Persistence and degradability	No data is available on the degradability of this product.
12.3. Bioaccumulative potential	No data available.
Partition coefficient n-octanol/water (log K_{ow})	Not available.
Bioconcentration factor (BCF)	Not available.
12.4. Mobility in soil	No data available.
12.5. Results of PBT and vPvB assessment	Not available.
12.6. Other adverse effects	Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 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.
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SECTION 15: Regulatory information

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

EU regulations

- Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I**
Not listed.
- Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II**
Not listed.
- Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended**
Not listed.
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended**
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended**
Not listed.
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended**
ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended**
Not listed.
- Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry**
Not listed.
- Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA**
Not listed.

Authorisations

- Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended**
Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

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

ETHYLMERCURITHIOSALICYLIC ACID SODIUM SALT (CAS 54-64-8)

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

Follow national regulation for work with chemical agents.

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

R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.
R26/27/28 Very toxic by inhalation, in contact with skin and if swallowed.
R33 Danger of cumulative effects.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
H300 Fatal if swallowed.
H310 Fatal in contact with skin.
H373 May cause damage to organs through prolonged or repeated exposure.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Revision information

Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Undisclosed Ingredient Statement
Physical & Chemical Properties:
Transport Information: Agency Name and Packaging Type/Transport Mode Selection
Regulatory Information: United States
GHS: Classification

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.