

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material	ENERGIX-B PRESERVATIVE FREE
Synonym(s)	ENERGIX-B ADOLESCENT PRESERVATIVE FREE * ENGERIX-B PAEDIATRIC PRESERVATIVE FREE * ENGERIX-B INFANT PRESERVATIVE FREE * ENGERIX-B PRESERVATIVE FREE 10 MCG/0.5 ML * ENGERIX-B PRESERVATIVE FREE 20 MCG/1 ML * ENGERIX-B ERWACHSENE AMPULLE MIT 1 ML SUSPENSION * ENGERIX-B ERWACHSENE FERTIGSPRITZE MIT 1 ML SUSPENSION * ENGERIX-B KINDER FERTIGSPRITZE MIT 0.5 ML SUSPENSION * NDC NO. 58160-820-11 * NDC NO. 58160-820-46 * NDC NO. 58160-821-11 * NDC NO. 58160-821-46 * HEPATITIS B SURFACE ANTIGEN VACCINE * HEPATITIS B (RECOMBINANT DNA) VACCINE (ADSORBED)
Company Name	<p>GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response</p> <p>GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

2. HAZARDS IDENTIFICATION

Fire and Explosion	This product is classified as non-flammable.
Health	Handling this product in its final form presents minimal risk from occupational exposure. May produce allergic skin reactions. Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing). Health effects information is based on hazards of components.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

* 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
HEPATITIS B VIRUS SURFACE ANTIGEN	Unassigned	Not Applicable	
NON-HAZARDOUS INGREDIENTS	Unassigned	> 99	

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4. FIRST-AID MEASURES

Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	None.
Medical Conditions Caused or Aggravated by Exposure	The components contained in this vaccine are generally not considered to cause disease in humans.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water is recommended for fires involving packaging.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	Water can be used for clean-up and decontamination operations. Sodium hypochlorite (bleach) or other strong oxidizers can be used in clean-up decontamination operations. Contaminated surfaces should be washed with water, then bleach or other oxidizing solution, followed by another water wash.

7. HANDLING AND STORAGE

HANDLING

General Requirements	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
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STORAGE

DO NOT FREEZE. Dispose of properly if frozen.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Other Equipment or Procedures	None required for normal handling. Wash hands and arms thoroughly after handling.
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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form	Liquid suspension.
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10. STABILITY AND REACTIVITY

Stability	DO NOT FREEZE - dispose of properly if frozen.
Conditions to Avoid	None for normal handling of this product.

11. TOXICOLOGY INFORMATION

Routes of Exposure

Oral Toxicity	Not expected to be toxic following ingestion.
Inhalation Toxicity	No studies have been conducted.
Skin Effects	Irritation is not expected following direct contact.
Eye Effects	Irritation is not expected following direct contact with eyes.
Sensitisation	Allergic skin reactions might occur following dermal exposure. Assessment based upon effects of structurally similar substances. Respiratory sensitisation (allergic) reactions might occur following exposure.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity	Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Other Adverse Effects	None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary	No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.
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13. DISPOSAL CONSIDERATIONS

Disposal Recommendations	The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.
Regulatory Requirements	Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Transport Information	Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.
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15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification	This product is exempt from the requirements of the OSHA Hazard Communication Standard.
Other US Regulations	
TSCA Status	Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

SDS Version Number 18

SDS Sections Updated**Sections****Subsections**

COMPOSITION / INFORMATION ON INGREDIENTS

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.