SAFETY DATA SHEET

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

Material
- ENGERIX-B

Synonyms
- ENGERIX B ADULT
- ENGERIX B PAEDIATRIC
- HEPATITIS B VACCINE, (RECOMBINANT)
- NDC NO. 58160-859-01
- NDC NO. 58160-859-11
- NDC NO. 58160-859-05
- NDC NO. 58160-859-06
- NDC NO. 58160-860-01
- NDC NO. 58160-860-16
- NDC NO. 58160-861-05

Company Name
- GlaxoSmithKline, Corporate Environment, Health & Safety
- 980 Great West Road
- Brentford, Middlesex TW8 9GS UK
- 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

- GlaxoSmithKline, Corporate Environment, Health & Safety
- 2200 Renaissance Blvd, Suite 105
- King of Prussia, PA 19406 US
- US General Information: +1-888-825-5249
- Transport Emergency (non EU) +1-703-527-3887
  US number, available 24 hours
  Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS RN</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>NON-HAZARDOUS INGREDIENTS</td>
<td>Unassigned</td>
<td>&gt;99</td>
</tr>
<tr>
<td>HEPATITIS B VIRUS SURFACE ANTIGEN</td>
<td>Unassigned</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

3. 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.

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.
STORAGE
No storage requirements necessary for occupational hazards.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance
Colour
White.
Physical Form
Suspension which might separate.

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

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.

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.

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.
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

None.


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

Date Approved/Revised 14-Aug-2003

SDS Version Number 12

SDS Sections Updated

Sections

ACCIDENTAL RELEASE MEASURES

Subsections

Clean-up Methods
Decontamination Procedures
Environmental Precautions
Personal Precautions
Spills

COMPOSITION / INFORMATION ON INGREDIENTS

DISPOSAL CONSIDERATIONS

Disposal Recommendations
GSK Standards and Guidance
Regulatory Requirements
Activated Sludge Respiration
Adsorption
Algal
Algal Degradation
Bioaccumulation
Biodegradation
Daphnid
Earthworm
Ecotoxicity
Fish
Hydrolysis
Microbial Growth Inhibition
Microtox
Mobility
Other Adverse Effects
Other Species - Aquatic
Other Species - Terrestrial
Partitioning
Persistence/Degradation
Photolysis
Solubility
Summary
SDS Sections Updated

Sections
ECOLOGICAL INFORMATION
EXPOSURE CONTROLS / PERSONAL PROTECTION

Subsections
Volutility
Administrative
Containment
Exposure Controls
Eye Protection
Gloves
Occupational Hygiene Air Monitoring Methods
Occupational Hygiene Surface Monitoring Method
Other Equipment or Procedures
Other Exposure Limits
Other Information
Other Protective Equipment
Respirators
Surface Exposure Target
Ventilation

FIRE-FIGHTING MEASURES
Extinguishing Media
Fire and Explosion Hazards
Hazardous Combustion Products
Special Firefighting Procedures

FIRST-AID MEASURES
Antidotes
Eye Contact
Health Surveillance Procedures
Ingestion
Inhalation
Medical Conditions Caused or Aggravated by
Medical Treatment
Skin Contact

HANDLING AND STORAGE
General Requirements
Handling
Ignition Controls
Protective Systems
Storage

HAZARDS IDENTIFICATION
Conditions Aggravated by Exposure
Environment
Eye Contact
Health
Ingestion
Inhalation
Overview
Skin Contact
Summary

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OTHER INFORMATION
Classification
Disclaimer Safety Data Sheet
Disclaimer Safety Summary
Disclaimer Technical Sheet
Information on Hazard Label
Nature of/Reason for Amendment
SDS Sections Updated
Sections
OTHER INFORMATION

Subsections
Other Information
References
Risk and Safety Phrases
SB Classification
Target Organ

REGULATORY INFORMATION

European Union Classification and Labelling
Other Regulations
Other US Regulations - California Proposition 65
Other US Regulations - TSCA Status
State Regulations
Summary
US Environmental (EPA) Requirements
US OSHA Standard (29 CFR Part 1910.1200) -

STABILITY AND REACTIVITY

Conditions to Avoid
Corrosivity
Hazardous Decomposition Products
Hazardous Polymerisation
Materials to Avoid
Stability
Thermal Stability

TOXICOLOGY INFORMATION

Carcinogenicity
Eye Effects
Genetic Toxicity
Inhalation Toxicity
Oral Toxicity
Other Adverse Effects
Pharmacological Effects
Reproductive Effects
Sensitisation
Skin Toxicity
Target Organ Effects

TRANSPORT INFORMATION

Class/Division
Emergency Action Code
Emergency Response Guide Number
EMS Number
European Ground Transport
Exceptions
Hazard Identification Number
Item
Marginal
Marine Pollutant
MFAG Number
NA Number
Packing Group
Packing Instructions
Proper Shipping Name
Reportable Quantity (RQ)
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.