

## SAFETY DATA SHEET



### \* 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

**Material** HIBERIX

**Synonym(s)** HIBERIX VACCINE \* NDC NO: 58160-806-01 \* NDC NO: 58160-806-05 \* HAEMOPHILUS TYPE B CONJUGATE VACCINE

**Company Name**

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Multi-language response

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US number, available 24 hours  
Multi-language response

### 2. HAZARDS IDENTIFICATION

**Fire and Explosion Hazards**

Expected to be non-combustible.

**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.
HAEMOPHILUS INFLUENZAE TYPE b CAPSULAR POLYSACCHARIDE	Unassigned	Not Applicable	
Other components below reportable levels		>99	

## 4. FIRST-AID MEASURES

<b>Ingestion</b>	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.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.
<b>Skin contact</b>	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.
<b>Eye contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

### NOTES TO HEALTH PROFESSIONALS

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

## 5. FIRE-FIGHTING MEASURES

<b>Fire and Explosion Hazards</b>	Not expected for the product, although the packaging is combustible.
<b>Extinguishing Media</b>	Water is recommended for fires involving packaging.
<b>Special Firefighting Procedures</b>	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.
<b>Hazardous Combustion Products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

## 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental Precautions</b>	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
<b>Clean-up Methods</b>	Spread an inert absorbent on the spill and place in a suitable, properly labelled container for recovery or disposal.
<b>Decontamination Procedures</b>	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

<b>HANDLING</b>	
<b>General Requirements</b>	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.
<b>STORAGE</b>	The recommended temperature for storage is 2-8 °C. Keep away from light.

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## 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** Lyophilised pellet.  
**Packaging** Vial.

## 10. STABILITY AND REACTIVITY

**Stability**

This product is expected to be stable.

**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.

## 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

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** 9

### SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	
IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY	

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