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### 1 Chemical product and company identification

#### 1.1 Product

Product: Hepatitis B Immune Globulin (Human)  
 Synonyms: Nabi-HB®  
 REACH-Classification: N/A

#### 1.2 Manufacturer

Company: Biotest Pharmaceuticals  
 5800 Park of Commerce Blvd., NW  
 Boca Raton, FL 33487

Telephone: 561-989-5800  
 Emergency Telephone Number  
 (InfoTrac) 352-332-3500

### 2 Hazards identification

Hepatitis B Immune Globulin (Human), Nabi-HB®, is a sterile solution of immunoglobulin containing antibodies to hepatitis B surface antigen (anti-HBs). Considered a biological product, Nabi-HB® is prepared from plasma donated by individuals with high titers of anti-HBs and is manufactured and distributed in accordance with the requirements of the United States Food and Drug Administration.

Biological products may contain infectious agents, such as viruses, that can cause disease. However, screening plasma donors for prior exposure to certain viruses and testing for the presence of certain viral infections has reduced the risk that this will occur. In addition, the manufacturing steps for Nabi-HB® are designed to reduce the risk of transmission of viral disease. Despite these measures, this biological product can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present. As with any biological product, this product also has the potential for causing rare allergic or anaphylactic reactions.

This material contains no carcinogens or potential carcinogens (as identified by IARC, NTP or OSHA) at 0.1% or greater concentration. This product is a "mixture" of USP and NF chemicals and purified water for which no health hazard data exists. This mixture is not known to present a health hazard.

### 3 Composition/Information on Ingredients

Components	OSHA PEL	ACGIH TLV	CAS Number
Human Immunoglobulin	N/A	N/A	N/A
Glycine	N/A	N/A	56-40-6
Sodium Chloride	N/A	N/A	7647-14-5
Polysorbate 80	N/A	N/A	9005-65-6
Water	N/A	N/A	7732-18-5

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#### **4 First aid measures**

Ingestion:	Seek medical consultation immediately. Medical consultant should be familiar with OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) and the current U.S. Public Health Service/CDC guidelines.
Inhalation (i.e. aerosols):	Seek medical consultation immediately. Medical consultant should be familiar with OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) and the current U.S. Public Health Service/CDC guidelines.
Intact Skin Contact:	Wash area well with soap and water. In the unlikely event that irritation persists, seek medical care.
Mucous Membrane/Percutaneous:	Flush area with water for 15 minutes. Seek (i.e. splashes to eyes, nose, mouth medical consultation immediately. Medical and/or needlesticks, cuts to skin) consultant should be familiar with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) and the current U.S. Public Health Service/CDC guidelines.
Note to Physician:	N/A

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#### **5 Fire-fighting measures**

Fire:	Not considered to be a fire hazard.
Explosion:	Not considered to be an explosion hazard.
Fire Extinguishing Media:	Noncombustible. Use extinguishing media appropriate to surrounding fire conditions.
Special Fire Fighting Procedures:	Use protective clothing and breathing equipment appropriate for the surrounding fire.

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#### **6 Accidental release measures**

Solutions of spilled materials can be taken up with absorbent material. Wear gloves and eye protection. Dispose of in accordance with local, state and federal regulations.

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#### **7 Handling and storage**

Store in original container in cool dry area between 2 - 8°C. Protect from physical damage.

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#### **8 Exposure controls and personal protection**

Utilize gloves and eye protection. Do not mouth pipette. Care must be taken when handling material in hypodermic syringes.

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## 9 Physical and chemical properties

Solubility in Water:	Complete
Specific Gravity:	N/A
Freezing Point:	N/A
Boiling Point:	N/A
Vapor Pressure:	N/A
Melting Point:	N/A
Vapor Density:	N/A
Evaporation Rate:	N/A
Odor:	Odorless
pH:	5.8 - 6.5
Appearance:	Clear to opalescent liquid

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## 10 Stability and reactivity

Stability:	Stable
Conditions to Avoid:	None known
Incompatibility (Materials to Avoid):	Strong oxidizing agents (sodium hypochlorite, hypochlorous acid, nitric acid)
Hazardous Decomposition Byproducts:	Glycine and Polysorbate 80 may decompose to carbon dioxide and carbon monoxide when heated to decomposition. Glycine may produce nitrogen oxides. When heated to above 804 °C sodium chloride emits toxic vapors of chloride and sodium oxide.
Hazardous Polymerization:	None known

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## 11 Toxicological information

None

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## 12 Ecological information

None

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## 13 Disposal considerations

Dispose of in accordance with local, state and federal regulations.

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## 14 Transport information

According to DOT and IATA regulations this material is considered a biological product and should be shipped accordingly.

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## 15 Regulatory information

The Food and Drug Administration has licensed this product.

**16 Other information**

Biotest Pharmaceuticals provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the product by properly trained personnel. Individuals receiving this information must exercise their independent judgment in determining its appropriateness for a particular purpose. BIOTEST PHARMACEUTICALS MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE INFORMATION SET FORTH HEREIN. ACCORDINGLY, BIOTEST PHARMACEUTICALS WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

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