



1.0 IDENTIFICATION OF THE PRODUCT AND COMPANY

Product Name Sci-B-Vac 10 mcg/ml
Prehevbrio 10 mcg/ml
PreHevbri 10mcg/ml

Synonyms Hepatitis B Surface Antigen Vaccine, HBsAg, recombinant HBsAg, r-HBsAg; recHBsAg, rDNA HBsAg, rDNA hepatitis B surface antigens

Recommended Use Medicinal Product (indicated for immunization against infection caused by hepatitis B virus).

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 to 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.

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2.0 HAZARD IDENTIFICATION

Hazard Classification	This product is regulated as a medicinal product and is not covered under the UN GHS, EU Directive 67/648/EEC and U.S. OSHA 29 CFR 1910.1200.
Label Elements	This product is regulated as a medicinal product and is not covered under the UN GHS, EU Directive 67/648/EEC and U.S. OSHA 29 CFR 1910.1200.
Other Hazards	This product is regulated as a medicinal product and is not covered under the UN GHS, EU Directive 67/648/EEC and U.S. OSHA 29 CFR 1910.1200.

3.0 COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures

Chemical Name	CAS #	Percent
Hepatitis B Surface Antigen	Unassigned	< 1
Aluminium Hydroxide	21645-51-2	< 1
Sodium Chloride	7647-14-5	< 1
Potassium Chloride	7447-40-7	< 1
Potassium Dihydrogen Phosphate	7778-77-00	< 1
Disodium Hydrogen Phosphate Dodecahydrate	10039-32-4	< 1
Water for Injections	7732-18-5	> 98

4.0 FIRST AID MEASURES

The Product is not considered to cause disease in humans.

Ingestion	Do not induce vomiting without advice from poison control center. Do not 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, rinse mouth with plenty of water. Obtain medical attention.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Remove contaminated clothing using appropriate personal protection and wash the exposed area with large amounts of water. Obtain medical attention if skin or other reaction occurs.
Eye Contact	Rinse immediately with clean and gently flowing water for at least 15 minutes. Obtain medical attention.

Indication of Immediate Medical Attention and Special Treatment Needed

No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance refer to the local Poison Control Information Center.



5.0 FIRE FIGHTING MEASURES

Fire and Explosion Hazard The Product is not classified as flammable or explosive.

Fire Extinguishing Media N/A

6.0 ACCIDENTAL RELEASE MEASURES

Personal Precaution Wear appropriate personal protection according to local requirements and regulations. No special protective equipment required. No personal respiratory protective equipment normally required.

Environmental Precautions Prevent large spills from entering into water supply, sewers and drainage.

Clean-Up Methods Collect and dispose according to relevant local legislation

Decontamination Wash hands before injection and immediately after handling the product.

7.0 HANDLING AND STORAGE

Precautions for Safe Handling No special control measures for normal handling are required.

Conditions for Safe Storage, including any Incompatibilities Store at $5\pm 3^{\circ}\text{C}$. Do not freeze. Dispose product if frozen.

8.0 EXPOSURE CONTROLS/ PERSONAL PROTECTION

Occupational Exposure Standards No exposure limits are listed.

Personal Protection Not required for normal handling of the Product. Wash hands after handling.

9.0 PHYSICAL AND CHEMICAL PROPERTIES

Physical State Liquid.

Form Suspension in a vial.

Color Turbid when mixed, clear colorless upper solution and white precipitate upon settling.



10.0 STABILITY AND REACTIVITY

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Stability	Stable at $5\pm 3^{\circ}\text{C}$. DO NOT FREEZE - dispose of properly if frozen.
Conditions to Avoid	None for normal handling of the product.

11.0 TOXICOLOGICAL INFORMATION

Route of Exposure

Oral	No studies have been performed.
Inhalation	No studies have been performed.
Skin	No studies have been performed.
Eye	No studies have been performed.
Genetic Toxicity	Not expected.
Carcinogenicity	Not expected.

Reproductive Effects	Not expected. Animal reproductive studies have not demonstrated deleterious effects with the Product. It is not known whether hepatitis B vaccines containing the Product can cause fetal harm when administered to pregnant women.
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12.0 ECOLOGICAL INFORMATION

The Product is not considered to result in adverse environmental effects. Dispose according to local regulations and requirements.

13.0 DISPOSAL CONSIDERATIONS

Dispose according to local regulations and requirements. Collect and dispose in sealed containers at licensed waste disposal site.

14.0 TRANSPORT INFORMATION

Transportation of this Product is not restricted. Not regulated as dangerous goods by IATA. No known significant hazard labeling or packaging requirements are needed.

15.0 REGULATORY INFORMATION

Product is regulated as a medicinal product.



16.0 OTHER INFORMATION

The above information describes exclusively the safety requirements of the product and is based on SciVac's present-day knowledge. SciVac, to the best of its knowledge, represents that the information and recommendations contained in this document are correct.

It is understood that the product supplied pursuant to this agreement is provided to recipient "as is" without and scivac makes no representations and extends no warranty of any kind, either express or implied, including, without limitation, any warranty of merchantability, title, fitness for a particular purpose or non-infringement of any patent, copyright, trademark or other proprietary rights.

To the fullest extent permitted by applicable law, and since the information contained in this safety data sheet may be applied under conditions beyond scivac's control, in no event shall scivac be liable to recipient, or any third party, for use, handling or storage by recipient of the product or for the information contained herein, or for any loss, injury, claim, damage or liability, of whatsoever kind or nature which may arise from recipient's use, handling, storage of the product or from any action or refraining from action by recipient as a result of this information.

The Recipient agrees to use of this Product in compliance with all applicable statutes, health and safety laws, treaties, orders and regulations and guidelines.

It is the responsibility of the recipient to determine the applicability of this information and the suitability of the material or product for any particular purpose and specific circumstances. The information is intended to give recipient advise on the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products.

MSDS – Recombinant Hepatitis B Surface
Antigen (r-HBsAg) Drug Product

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