

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

Trade Name:

Hepatitis B Virus Surface Antigen (adr), Recombinant (HBsAg)

Revision 000
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1. **IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY UNDERTAKING**
Identification of the Substance or Preparation: Hepatitis B Virus Surface Antigen (adr), Recombinant (HBsAg)
REACH Registration No: Not Applicable
Use of the Substance / Preparation:
Identified Use(s): For *in vitro* laboratory use. For professional use only.
Company Undertaking Identification:
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2. HAZARDS CLASSIFICATION

Classification: Void

Information Pertaining to Special Dangers for Human and Environment:

This mixture does not require labeling, based on the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest version. This mixture is not classified as hazardous according to the EC Dangerous Preparations Directive (1999/45/EC) or EC 1272/2008 (CLP).

Classification System:

The classification is in alignment with current EC (European Community) Directives. It is expanded with information from technical literature.

Physical Hazards: Not classified as a physical hazard.

Health Hazard: Not classified as a health hazard.

Environmental Hazard: Not classified as environmental hazard.

Precautionary Statements: The chemical, physical and toxicological properties of this mixture have not been thoroughly characterized. Avoid contact with eyes and skin. Do not inhale. This material was originally

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sourced from Rubella Virus (HPV77 strain) infected VERO cells cultured in the presence of fetal bovine serum. All animal sources were sourced and qualified from United States to be free from BSE/TSE, which were used in the manufacture of this product. This material should be considered as potentially capable of transmitting infectious disease.

Potential Health Effects:

Inhalation: No data available.
Eyes: No data available. Eye exposure may cause irritation, redness and watering.
Skin: No data available.
Ingestion: No data available.
Chronic Effects: No data available.
Target Organs: No data available.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Characterization (Hazardous Chemical Ingredients):

Dangerous Components According to EC Criteria: There are no classified ingredients, or those having occupational exposure limits, present above the levels of disclosure.

Additional Information: For wording of the listed risk phrases, refer to Section 16.

All materials should be handled as infectious. Generally accepted laboratory practices appropriate for infectious materials should be employed when handling this product

4. FIRST AID MEASURES

In Case of Inhalation: Remove from source of exposure. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop. When exposed to large amounts of steam and mist, move to fresh air.

In Case of Skin Contact: Remove clothing that product has touched. Rinse skin for 15 minutes. Seek medical attention if irritation persists. Wash contaminated clothing before re-using.

In Case of Eye Contact: Do not rub your eyes. Immediately flush with water for a minimum of 15 minutes. Remove contact lenses if worn. Obtain medical attention if redness or irritation persists

In Case of Ingestion: Rinse mouth with water. Seek medical attention if signs of toxicity occur.

Self-Protection of the First Aider: Follow company specific safety procedures.

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5. FIRE FIGHTING MEASURES

Suitable Extinguishing Media: Dry chemical, carbon dioxide, regular foam extinguishing agent, spray
Extinguishing Media Which Must Not Be Used for Safety Reasons: Avoid use of water jet for extinguishing
Special Exposure Hazards Arising From the Substance or Preparation Itself, Combustion Products, Resulting Gases: Dilute aqueous solution not considered a fire hazard.

Special Protective Equipment for Fire-Fighters:

Fire fighters should wear NIOSH-approved or self-contained breathing apparatus and full protective gear.

- Avoid inhalation of materials or combustion by-products.
- Cool containers with water until well after fire is out.
- Do not approach the tank surrounded by fire until it is extinguished.
- In case of conflagration, use automatic fire sprinkler. Major fire may require withdrawal, allowing the object itself to burn.
- Keep unauthorized personnel out.
- Move containers from fire area, if you can do without the risk.
- Notify your local fire station and inform the location of the fire and characteristics hazard.
- Use appropriate extinguishing measure suitable for surrounding fire.
- Wear appropriate protective equipment.
- Withdraw immediately in case of rising sound from venting safety devices or discoloration of tank

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: See Section 8.

- **For Non-emergency personnel:** Wear proper protective equipment.
- **For emergency responders:**
 - Wear personal protective equipment and avoid skin contact and inhalation.
 - Do not direct water at spill or source of leak.
 - Do not touch spilled material. Stop leak if you can without risk.
 - Handle the damaged containers or spilled material after wearing appropriate personal protective equipment.
 - Move container to safe area from the leak area.
 - Must work against the wind, let upwind people to evacuate.
 - Remove all sources of ignition.
 - Ventilate closed spaces before entering.

Environmental Precautions: This product contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing system and form potentially explosive metal azides. Follow proper disposal procedures.

Methods for Cleaning Up:

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For Containment:

- Clean up all spills immediately.
- Clear area of personnel and move up wind.
- Clear spills immediately
- Control personal contact by using protective equipment.
- Don't use a brush or compressed air for cleaning surfaces or clothing.
- No smoking, flame or ignition sources.
- Prevent, by any means available, spillage from entering drains or water course.
- Stop leak if safe to do so.

For Cleaning Up:

- Appropriate container for disposal of spilled material collected.
- Dike for later disposal.
- Disposal of waste shall be in compliance with the Wastes Control Act
- Large spill : Stay upwind and keep out of low areas. Dike for later disposal.
- Notify the central and local government if the emission reach the standard threshold.
- Small leak: sand or other non-combustible material, please let use absorption.
- Wipe off the solvent.

Other information:

- Material is slippery when spilled

7. HANDLING AND STORAGE

Handling:

- Follow good laboratory hygiene practices.
- Avoid contact with incompatible materials.
- Avoid direct physical contact.
- Comply with all applicable laws and regulations for handling
- Dealing only with a well-ventilated place.
- Do not handle until all safety precautions have been read and understood.
- Do not inhale the steam prolonged or repeated.
- Get the manual before use.
- Operators should wear antistatic footwear and clothing.
- Refer to Engineering controls and personal protective equipment.
- Since emptied containers retain product residue(vapor, liquid, solid) follow all MSDS and label warnings even after container is emptied
- Wash thoroughly after handling

Storage:

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- Avoid direct sunlight.
- Check regularly for leaks.
- Do not apply any physical shock to container.
- Do not apply direct heat.
- Do not use damaged containers.
- Keep in the original container.
- Keep sealed when not in use.
- No open fire.
- Please pay attention to incompatibilities materials and conditions to avoid.
- Prevent static electricity and keep away from combustible materials or heat sources.
- Save in cool, dry and well ventilated place.
- Store according to current laws and regulations

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limit Values: Not available

Exposure Controls: Business owner is recommended to maintain below recommended exposure limits for the working place with general exhaust of gas/vapor/mist/fume.

Personal Protection Equipment:

Respiratory Protection:

- Any air-purifying respirator with a full facepiece and an organic vapor canister.
- Any chemical cartridge respirator with a full facepiece and organic vapor cartridge(s).
- Any chemical cartridge respirator with organic vapor cartridge(s).
- Consider warning properties before use.
- For Unknown Concentration or Immediately Dangerous to Life or Health : Any supplied-air respirator with full facepiece and operated in a pressure-demand or other positive-pressure mode in combination with a separate escape supply. Any self-contained breathing apparatus with a full facepiece.

Hand Protection: Wear chemical resistant protective gloves.

Eye Protection

- Provide an emergency eye wash station and quick drench shower in the immediate work area.
- Wear primary eye protection such as splash resistant safety goggles with a secondary protection face shield.

Body Protection: Wear lab coat or other protective garments. Remove contaminated clothing promptly

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Liquid

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Physical State: Liquid

Color: Not Available

Odor: Not Available

Parameter	Value
pH (20°C):	Not Available
Melting Point/Range (°C):	Not Available
Boiling Point/Range (°C):	Not Available
Flash Point (°C):	Not Applicable
Ignition Temperature (°C):	Not Applicable
Vapor Pressure (°C):	Not Available
Density (g/cm³):	Not Available
Bulk Density (kg/m³):	Not Available
Water Solubility (20°C in g/L):	Fully Miscible
Partition Coefficient	
n-Octanol/Water (log Po/w):	Not Available
Viscosity, Dynamic (mPa s):	Not Available
Dust Explosion Hazard:	Not Applicable

10. STABILITY AND REACTIVITY

Reactivity: Unknown.

Stability: Stable under ordinary conditions of storage and use.

Possibility of Hazardous situations: Hazardous Polymerization will not occur.

Conditions to Avoid:

- Avoid Accumulation of electrostatic charges, Heating, Flames and hot surfaces
- Avoid contact with incompatible materials and condition.

Materials to Avoid: Not Available

Hazardous Decomposition Products: May emit flammable vapor if involved in fire.

11. TOXICOLOGICAL INFORMATION

Routes of exposure may include inhalation, skin absorption, and eye and skin contact.

Acute Toxicity: No data available.

Irritant and Corrosive Effects: No data available.

Sensitization: No data available.

Carcinogenicity: No data available. None of the components in this product at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

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Mutagenicity: No data available.

Reproductive Effects: No data available.

Teratogenicity: No data available.

Additional Toxicological Information: This product is not subject to classification, according to the calculation method of the General EC Classification Guidelines for preparations as issued in the latest version. When used and handled according to specifications, the product does not have any harmful effects according to our experience and information available to us.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

- Fish:
[Sodium chloride] : LC50 5840 mg/L 96 hr *Lepomis macrochirus* (ECHA)
- Invertebrate:
[Sodium chloride] : LC50 874 mg/L 48 hr *Daphnia magna* (ECHA)
- Algae: Not available
[Sodium chloride] : EC50 2430 mg/L 120hr *Nitzschia* sp. (ECHA)

Mobility in Environmental Compartments: No data available.

Adsorption/Desorption: No data available.

Persistence and Degradability: No data available.

Physical- and Photo-Chemical Elimination: No data available.

Biodegradation: No data available.

Bio accumulative Potential: No data available.

13. DISPOSABLE CONSIDERATIONS

Appropriate Disposal / Product:

- It shall be treated by incineration
 - Oil water separation shall be applied as a pre-waste treatment if it is applicable
 - Stabilization and minimization treatment by incineration or similar method can be applied, if more than two kinds of designated wastes are in mixture state and it is impractical to separate them
 - Anyone with business license number who generates industrial wastes shall treat the waste by him/herself or by entrusting to the legal entities who treat the wastes, recycle the wastes of others or install and operate the waste treatment facilities according to the Wastes Control Act
 - Dispose of waste in accordance with all applicable laws and regulations
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14. TRANSPORT INFORMATION

Land Transport (ADR/RID/GGVSE):

- Local transport follows in accordance with Dangerous goods safety management law.
- Package and transport follow in accordance with Department of Transportation (DOT) and other regulatory agency requirements.
- Tunnel Restriction Code
- Hazard No. (ADR)
- Emergency Action Code

Sea Transport (IMDG-Code/GGVSee): Not restricted. Not regulated as hazardous goods.

Air Transport (ICAO-IATA/DGR): Not restricted. Not regulated as hazardous goods

15. REGULATORY INFORMATION

EU Regulations: Not Applicable

Chemical Safety Assessment: Observe general laboratory safety regulations when handling chemicals. This product is not subject to identification regulations under EC Directives

16. OTHER INFORMATION

Exposure Scenarios:

Routes of exposure may include inhalation, skin absorption, and eye and skin contact.

Exposure Controls:

Observe general laboratory safety regulations when handling chemicals. This product is not expected to require special ventilation controls. Facilities storing or using this product should be equipped with an eyewash fountain.

Personal Protection Equipment:

Respiratory Protection: A respirator is not expected to be required under normal conditions of use. Hand Protection: Wear chemical resistant protective gloves.

Eye Protection: Wear appropriate protective safety eyeglasses or goggles.

Body Protection: Wear lab coat or other protective garments. Remove contaminated clothing promptly

This Safety Data Sheet (SDS) was prepared in accordance with the hazard criteria and content requirements of the EU Dangerous Substances Directive (67/548/EEC), Dangerous Preparations Directive (1999/45/EC), the Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) ((EC) No 1907/2006) and EC 1272/2008 Classification, Labeling, Packaging (CLP). These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. The information contained in this SDS is believed to be accurate but does not purport to be all inclusive and should be used only as a guide for experienced personnel.



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It is the responsibility of the user or supplier to determine the applicability of the data to the formulation of necessary safety precautions. Meridian Life Science, Inc. shall not be held liable for any damage resulting from the use of the above product or the information contained in this SDS.