

MSDS

Revision: 001

Revision Date: 15 FEB 2025

Trade Name: Human Chorionic Gonadotropin, Beta Subunit (b-hCG), Native

## Section 1: Identification of the Substance/Mixture and Company

| Item                      | Details                                                                                                                                                                                  |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Product Identifier</b> | Human Chorionic Gonadotropin, Beta Subunit (b-hCG), Native                                                                                                                               |
| <b>Other Names</b>        | Beta-human chorionic gonadotropin, b-hCG, CG-beta, Choriogonadotropin subunit beta                                                                                                       |
| <b>Catalog Number</b>     | 325-11-NZN                                                                                                                                                                               |
| <b>CAS Number</b>         | 9002-61-3                                                                                                                                                                                |
| <b>Molecular Weight</b>   | ~22,200 Da ( $\beta$ -subunit)                                                                                                                                                           |
| <b>Recommended Use</b>    | For in-vitro diagnostic (IVD) applications, immunoassay development (ELISA, CLIA, Rapid Test), calibration, quality control, and laboratory research purposes                            |
| <b>Prohibited Uses</b>    | Not for in-vivo therapeutic or diagnostic use in humans or animals. Not for injection, oral consumption, or any medical application involving direct administration to humans or animals |
| <b>Manufacturer</b>       |                                                                                                                                                                                          |
| <b>Company Name</b>       | Nojan Zist Fanavaran Co.                                                                                                                                                                 |
| <b>Address</b>            | Tehran, Velenjak, Daneshjoo Blvd., Edalat St., Avran Tower, Comprehensive Applied Science Center, No. 0, Health Technology & Incubation Center, Iran                                     |
| <b>Telephone</b>          | +98-930-600-4641                                                                                                                                                                         |
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## Section 2: Hazard Identification



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| Category                      | Information                                                                                                                                                                                                                                                                                                             |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| GHS Classification            | Non-hazardous (at supplied concentration and intended laboratory use)                                                                                                                                                                                                                                                   |
| Physical and Chemical Hazards | None identified                                                                                                                                                                                                                                                                                                         |
| Signal Word                   | None                                                                                                                                                                                                                                                                                                                    |
| Hazard Statements             | None                                                                                                                                                                                                                                                                                                                    |
| Biological Safety Note        | Donor material (human pregnancy urine) has been tested and found negative for anti-HIV-1, anti-HIV-2, anti-HCV, and HBsAg using FDA-approved methods. However, no test can provide 100% assurance of the absence of infectious agents. This product should be handled as potentially infectious human-derived material. |

#### Precautionary Statements:

| Category   | Precautionary Measures                                                                                                                                                                                         |
|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Prevention | Handle as potentially infectious human-derived material. Avoid contact with skin, eyes, and mucous membranes. Do not inhale aerosols; avoid aerosol generation. Use appropriate personal protective equipment. |
| Response   | Follow first aid measures outlined in Section 4.                                                                                                                                                               |
| Storage    | Store at 2–8°C in a dry place, protected from light. Avoid freezing.                                                                                                                                           |
| Disposal   | Dispose of as potentially infectious biological waste in accordance with national and local regulations (see Section 13).                                                                                      |



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### Potential Health Effects:

| Route of Exposure | Potential Effect                                                    |
|-------------------|---------------------------------------------------------------------|
| Inhalation        | No data available. May cause respiratory irritation if aerosolized. |
| Skin Contact      | May cause mild irritation in sensitive individuals.                 |
| Eye Contact       | May cause redness and tearing.                                      |
| Ingestion         | No data available.                                                  |
| Chronic Effects   | No data available.                                                  |

### Section 3: Composition/Information on Ingredients

| Component                                          | CAS Number | Function / Role                                                                 | Concentration                                                       |
|----------------------------------------------------|------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Human Chorionic Gonadotropin, Beta Subunit (b-hCG) | 9002-61-3  | Main active substance (human origin)                                            | $\geq 98\%$ purity (protein content: $\geq 1$ mg/mg solid by ELISA) |
| Ammonium Bicarbonate                               | 1066-33-7  | Lyophilization buffer (removed during lyophilization; trace amounts may remain) | < 1% (residual)                                                     |

**Note:** The product is supplied as a lyophilized powder from 50 mM ammonium bicarbonate buffer. The buffer component is largely removed during lyophilization, with only trace amounts potentially remaining. No preservatives or stabilizers are added.

### Section 4: First Aid Measures

| Route of Exposure   | First Aid Measures                                                                                                                                                                         |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Inhalation</b>   | Move to fresh air. Seek medical attention if irritation or symptoms persist.                                                                                                               |
| <b>Skin Contact</b> | Remove contaminated clothing. Wash affected area with soap and plenty of water for at least 15 minutes. Seek medical attention if irritation persists.                                     |
| <b>Eye Contact</b>  | Rinse immediately with plenty of water for at least 15 minutes, lifting eyelids occasionally. Remove contact lenses if present and easy to do. Seek medical advice if irritation persists. |
| <b>Ingestion</b>    | Rinse mouth with water. Do not induce vomiting. Seek medical attention if symptoms occur.                                                                                                  |

## Section 5: Fire-Fighting Measures

| Item                                  | Information                                                                                                                           |
|---------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| <b>General Information</b>            | The product is not flammable.                                                                                                         |
| <b>Suitable Extinguishing Media</b>   | Carbon dioxide (CO <sub>2</sub> ), dry chemical powder, foam, water spray                                                             |
| <b>Unsuitable Extinguishing Media</b> | None specified                                                                                                                        |
| <b>Specific Hazards</b>               | Not combustible. In case of fire, may release hazardous decomposition products including nitrogen oxides, carbon oxides, and ammonia. |
| <b>Firefighter Protection</b>         | Wear self-contained breathing apparatus (SCBA) and full protective clothing.                                                          |

## Section 6: Accidental Release Measures

| Category                         | Measures                                                                                                                                                                                                                                                                                                                                                |
|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Personal Precautions</b>      | Wear appropriate personal protective equipment (gloves, lab coat, eye protection). Avoid aerosol formation. Evacuate non-essential personnel.                                                                                                                                                                                                           |
| <b>Environmental Precautions</b> | Prevent entry into drains, sewers, or water sources.                                                                                                                                                                                                                                                                                                    |
| <b>Cleanup Methods</b>           | <ul style="list-style-type: none"> <li>• Absorb spilled material with inert absorbent material (e.g., paper towels, vermiculite).</li> <li>• Decontaminate the area with 10% bleach or an appropriate virucidal disinfectant per laboratory SOP.</li> <li>• Collect all cleanup materials in a biohazard container for appropriate disposal.</li> </ul> |

## Section 7: Handling and Storage

### Handling

- Use Biosafety Level 2 (BSL-2) practices for handling human-derived materials.
- Wear appropriate personal protective equipment (nitrile/latex gloves, laboratory coat, safety goggles).
- Do not pipette by mouth.
- Avoid generation of aerosols; use a biosafety cabinet if aerosol formation is possible.
- Wash hands thoroughly after handling.

### Storage

- Store tightly sealed in original container at 2–8°C.
- Protect from light and moisture.
- Avoid freezing.
- For long-term storage, maintain recommended conditions.
- After reconstitution, store according to specific product guidelines and use promptly.

## Section 8: Exposure Controls/Personal Protection

| Category | Recommendation |
|----------|----------------|
|----------|----------------|

|                                  |                                                                                                                                                    |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Eye/Face Protection</b>       | Safety goggles or face shield                                                                                                                      |
| <b>Skin Protection</b>           | Nitrile or latex gloves, laboratory coat                                                                                                           |
| <b>Respiratory Protection</b>    | Normally not required. Use a biosafety cabinet or appropriate respirator (e.g., N95) if aerosol formation is possible or based on risk assessment. |
| <b>Hygiene Measures</b>          | Do not eat, drink, or smoke when using this product. Always wash hands after handling.                                                             |
| <b>Environmental Precautions</b> | Prevent release to drains.                                                                                                                         |

## Section 9: Physical and Chemical Properties

| Property                                       | Information                                               |
|------------------------------------------------|-----------------------------------------------------------|
| <b>Appearance</b>                              | White to off-white lyophilized powder                     |
| <b>Color</b>                                   | White to off-white                                        |
| <b>Odor</b>                                    | Odorless                                                  |
| <b>pH (reconstituted)</b>                      | 7.0–7.4 (dependent on reconstitution buffer)              |
| <b>Melting/Freezing Point</b>                  | Not applicable (lyophilized powder)                       |
| <b>Boiling Point</b>                           | Not applicable                                            |
| <b>Flash Point</b>                             | None                                                      |
| <b>Solubility</b>                              | Fully soluble in water and neutral pH buffers (PBS, Tris) |
| <b>Auto-ignition Temperature</b>               | Not applicable                                            |
| <b>Decomposition Temperature</b>               | No data available                                         |
| <b>Explosive Properties</b>                    | None                                                      |
| <b>Oxidizing Properties</b>                    | None                                                      |
| <b>Vapor Pressure</b>                          | Not applicable                                            |
| <b>Relative Density</b>                        | Not applicable                                            |
| <b>Partition Coefficient (n-octanol/water)</b> | No data available                                         |

## Section 10: Stability and Reactivity

| Category | Information |
|----------|-------------|
|----------|-------------|



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|                                         |                                                                                                              |
|-----------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Reactivity</b>                       | Not reactive under normal conditions of use and storage.                                                     |
| <b>Stability</b>                        | Stable when stored under recommended conditions (2–8°C, dry, protected from light).                          |
| <b>Conditions to Avoid</b>              | Freezing, extreme heat, prolonged exposure to light, repeated reconstitution and lyophilization cycles.      |
| <b>Incompatible Materials</b>           | Strong acids, strong bases, strong oxidizing agents, heavy metal ions.                                       |
| <b>Hazardous Decomposition Products</b> | None under normal conditions. Thermal decomposition may produce carbon oxides, nitrogen oxides, and ammonia. |

## Section 11: Toxicological Information

| Category                                            | Information                                                                                                         |
|-----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| <b>Acute Toxicity</b>                               | Low expected; protein-based material generally non-toxic. No data available for oral, dermal, or inhalation routes. |
| <b>Skin Irritation</b>                              | May cause mild irritation in sensitive individuals.                                                                 |
| <b>Eye Irritation</b>                               | May cause mild irritation, redness, or tearing.                                                                     |
| <b>Respiratory Irritation</b>                       | May cause irritation if inhaled as aerosol.                                                                         |
| <b>Sensitization</b>                                | No data available.                                                                                                  |
| <b>Mutagenicity</b>                                 | No data available; not expected based on protein nature.                                                            |
| <b>Carcinogenicity</b>                              | No data available; not expected.                                                                                    |
| <b>Reproductive Toxicity</b>                        | No data available.                                                                                                  |
| <b>Specific Organ (STOT)</b> <b>Target Toxicity</b> | No data available.                                                                                                  |

**Note:** The primary active ingredient is a human protein and is not considered toxic. However, as with all biological materials, appropriate handling precautions should be observed.

## Section 12: Ecological Information

| Category           | Information                                               |
|--------------------|-----------------------------------------------------------|
| <b>Ecotoxicity</b> | No data available. Protein-based material; expected to be |

|                                      |                                                                                                             |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------|
|                                      | biodegradable.                                                                                              |
| <b>Persistence and Degradability</b> | Protein component is expected to be biodegradable.                                                          |
| <b>Bioaccumulation Potential</b>     | Not expected due to protein nature.                                                                         |
| <b>Mobility in Soil</b>              | No data available.                                                                                          |
| <b>PBT/vPvB Assessment</b>           | Not classified as PBT (Persistent, Bioaccumulative, Toxic) or vPvB (very Persistent, very Bioaccumulative). |

**Environmental Precautions:** Prevent entry into drains and water sources.

### Section 13: Disposal Considerations

| Category                      | Information                                                                                                                                                                                  |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Waste Disposal Method</b>  | Dispose of contents and container as potentially infectious biological waste in accordance with national and local regulations. Incineration is recommended where approved facilities exist. |
| <b>Contaminated Packaging</b> | Treat as biohazardous waste and dispose of accordingly.                                                                                                                                      |
| <b>Regulatory Compliance</b>  | Follow all applicable local, national, and international regulations for disposal of biological materials.                                                                                   |

### Section 14: Transport Information

| Category                     | Information                                                                         |
|------------------------------|-------------------------------------------------------------------------------------|
| <b>Hazard Classification</b> | Not regulated as dangerous goods for transport (at supplied concentration and form) |



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|                                       |                                                                               |
|---------------------------------------|-------------------------------------------------------------------------------|
| <b>UN Number</b>                      | Not applicable                                                                |
| <b>UN Proper Shipping Name</b>        | Not applicable                                                                |
| <b>Transport Hazard Class</b>         | None                                                                          |
| <b>Packing Group</b>                  | None                                                                          |
| <b>Environmental Hazards</b>          | None                                                                          |
| <b>Special Precautions</b>            | Maintain cold chain (2–8°C) during transport. Avoid temperature fluctuations. |
| <b>Transport in Bulk (MARPOL/IMO)</b> | Not applicable                                                                |

## Section 15: Regulatory Information

| Category                            | Information                                                                                                                                                                                                                                                                                   |
|-------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>National Regulations (Iran)</b>  | Subject to oversight by the General Directorate of Medical Equipment (IMED system) as a human-derived in-vitro diagnostic material. Registration requires technical dossier, donor screening documentation, and compliance with quality management systems (e.g., ISO 13485, GMP principles). |
| <b>International Inventories</b>    | For export/import purposes, registration in relevant inventories (EINECS/ELINCS, TSCA, IECSC, etc.) may be required based on target market and product classification.                                                                                                                        |
| <b>GHS Status</b>                   | Not classified as hazardous under Globally Harmonized System (GHS) at supplied concentration and form.                                                                                                                                                                                        |
| <b>Safety Data Sheet Compliance</b> | This MSDS complies with applicable requirements of REACH, OSHA Hazard Communication Standard (29 CFR 1910.1200), and relevant national regulations.                                                                                                                                           |

## Section 16: Other Information

| Category           | Information |
|--------------------|-------------|
| <b>Preparation</b> | 15 FEB 2026 |



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|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Date</b>             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Revision Summary</b> | Initial release (Revision 001)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Prepared By</b>      | Quality Assurance Department, Nojan Zist Fanavaran Co.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Abbreviations</b>    | BSL-2: Biosafety Level 2; COA: Certificate of Analysis; ELISA: Enzyme-Linked Immunosorbent Assay; CLIA: Chemiluminescence Immunoassay; GHS: Globally Harmonized System; GMP: Good Manufacturing Practices; HIV: Human Immunodeficiency Virus; HCV: Hepatitis C Virus; HBsAg: Hepatitis B Surface Antigen; IMED: Iran Medical Equipment Directory; IVD: In Vitro Diagnostic; MSDS: Material Safety Data Sheet; PBT: Persistent, Bioaccumulative, Toxic; PPE: Personal Protective Equipment; SCBA: Self-Contained Breathing Apparatus; SOP: Standard Operating Procedure; vPvB: very Persistent, very Bioaccumulative |
| <b>Disclaimer</b>       | The information contained in this Material Safety Data Sheet is based on current knowledge and experience and is provided for health, safety, and environmental purposes only. It does not constitute a guarantee or warranty of product properties. Users should make their own assessments and establish appropriate safe handling procedures for their specific applications and conditions of use. Nozhan Zist Fanavaran Co. assumes no liability for any damages or losses resulting from the use of or reliance on this information.                                                                          |