

SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product Name: Recombinant Rheumatoid Factor
Product Number: BSP46000-10, BSP46000-50, BSP46000-450, BSP46000-1000, BSP46000-BULK
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2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.
Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC.

2.2 Label elements

The product does not need to be labelled in accordance with EC directives or respective national laws.

2.3 Other hazards

This product does not contain substances listed on the ECHA Candidate list or identified as an endocrine disruptor as defined in Delegated Regulations (EC) 2017/2100 or (EC) 2018/605

3. COMPOSITION/INFORMATION ON INGREDIENTS

Human monoclonal IgM antibody produced recombinantly in human HEK293 cell line.

Additional components present: TRIS- buffered saline (0.15M NaCl, 20mM Tris(hydroxymethyl)-aminomethane (commonly known as TRIS) pH7.5), residual HEK293 host cell protein, residual growth media (Gibco Freestyle 293).

4. FIRST AID MEASURES

If inhaled: If breathed in, move person into fresh air. If not breathing give artificial respiration.



Consult a physician.

In case of skin contact:

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact:

Rinse thoroughly at eyewash station for at least 15 minutes and consult a physician.

If swallowed:

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special protective equipment for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

Wear gloves and eye protection.

Environmental precautions

Prevent further leakage or spillage if safe to do so.

Methods and materials for containment and cleaning up

Pick up using absorbent tissue and arrange for safe disposal. Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Avoid contact with skin and eyes.

Conditions for safe storage

Recommended storage temperature: -20 to -80 °C for long term.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection

None necessary.

Hand protection



The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
Handle with gloves.

Eye protection

Safety glasses

Skin and body protection

Laboratory coat

Hygiene measures

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information of basic physical and chemical properties

Physical State:	Slightly opaque liquid
Colour:	Colourless, can have a slight amber or brown tinge.
Odour:	no data available
Odour Threshold (ppm):	no data available
pH (Value):	7.0 – 7.8
Melting Point (°C) / Freezing Point (°C):	no data available
Boiling point/boiling range (°C):	no data available
Flash Point (°C):	no data available
Evaporation rate (BA = 1):	no data available
Flammability (solid, gas):	no data available
Explosive limit ranges:	no data available
Vapour Pressure (mm Hg):	no data available
Vapour Density (Air=1):	no data available
Density (g/ml):	no data available
Solubility (Water):	soluble
Solubility (Other):	no data available
Partition Coefficient (n-Octanol/water):	no data available
Auto Ignition Temperature (°C):	no data available
Decomposition Temperature (°C):	no data available
Viscosity (mPa.s):	no data available
Explosive properties:	no data available
Oxidising properties:	no data available

9.2 Other information

no data available



10. STABILITY AND REACTIVITY

Chemical stability

Stable under recommended storage conditions.

Conditions to avoid

Avoid multiple freeze thaw cycles

Materials to avoid

Strong oxidizing agents

Hazardous decomposition products

None known

11. TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity:

no data available

Skin corrosion/irritation

no data available

Serious eye damage/eye irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

no data available

Aspiration hazard

no data available

Potential health effects

Inhalation May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion May be harmful if swallowed.



Skin	May be harmful if absorbed through skin. May cause skin irritation.
Eyes	Causes eye irritation.

Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Additional Information

RTECS: No data available

11.2 Information on other hazard classes which relates to endocrine disrupting properties.

Not applicable

12. ECOLOGICAL INFORMATION**Toxicity**

no data available

Persistence and degradability

no data available

Bioaccumulative potential

Low

Mobility in soil

no data available

PBT and vPvB assessment

no data available

Endocrine disrupting properties

no data available

Other adverse effects

no data available

13. DISPOSAL CONSIDERATIONS**Product**

Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

Not dangerous goods, no transport limitations.

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

16. OTHER INFORMATION

Take special care when working in conjunction with hypodermic needles. If i.v. or i.m. injection should occur, consult a physician.

Last updated: 26/09/2025

Prepared by: The Native Antigen Company

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