Proliant NEW ZEALAND LTD

Bovine Serum Albumin Reagent Grade, Fatty Acid Free Powder Protease Free and Low Endotoxin

Proliant NZ Ltd Bovine Serum Albumin (BSA) is a high purity, lyophilized "Fraction V" powder derived from the plasma of MPI-inspected healthy New Zealand origin animals. The albumin is isolated from other plasma protein products and lipids by a unique proprietary, non-solvent procedure. The separation process includes a modified Cohn / heat-shock procedure designed to inactivate proteases and other potentially interfering enzymes. Further processing such as extensive membrane dialysis and filtration (including charcoal filtration), minimizes analytes including nonesterified fatty acids, that can cause background interference in sensitive in vitro diagnostic (IVD) assays as well as inhibition in sensitive cell and microbial culture systems. Typical purity levels are in excess of 99%. Proliant's New Zealand Sourced Reagent Grade, Fatty Acid Free bovine albumin product is ideal for the most sensitive diagnostic and research applications.

APPLICATIONS

- Protease-sensitive Immunoassays such as RIA, EIA, Fluorescent and Chemiluminescent
- Protein Standard, Diluent
- Protein, Conjugate or Enzyme Stabilizer
- Hybridization, nucleic acid-based assays
- Fatty acid sensitive cell culture systems

FEATURES / BENEFITS

- High Purity, Low Interference, Low Background
- Virtually No Detectable Protease Activity, Ensures Assay Integrity
- Origin Traceability to Facilitate Regulatory Approval
- "Closed Loop" Manufacturing*
 - Minimizes Contamination and Maximizes Reproducibility
- Superior Solubility/Filterability for Ease of Use
- Product Development and Technical Services designed for maximum responsiveness and Flexibility.
- Manufactured from MPI inspected Bovine
 Plasma
- Manufactured According to FDA cGMPs
- Validated for Prion (TSE) Clearance
- MPI Health Certificate
- · USDA/APHIS registered for Shipment to the US

SCIENTIFIC ANALYSIS

Specification

Typical Values

Protein (dry basis) Purity (albumin)	≥ 98% ≥ 98%	99.0% 100%
Solubility (4% water)	Clear/slightly hazy	Clear/slightly hazy
Moisture	≤ 5.0%	< 2%
pH (10% water)	6.5-7.5	6.8-7.2
Ash	< 2%	1%
Protease	≤ 0.005 Units/mg	≤ 0.005 Units/mg
NEFA	<0.01%	<0.005%vvvv
Bovine IgG	Not Detected	Not Detected
Endotoxin	≤ 3 EU/mg	0.1 EU/mg
Heavy Metals (Pb)	≤ 10 ppm	< 1 ppm

Na. Cl, K, P, Ca are tested and can be reported on the Certificate of Analysis if requested

PHYSICAL CHARACTERISTICS

Proliant NZ Bovine Serum Albumin is a highly soluble yellow to green with tan to green cast lyophilized powder. A solution of up to 30% in de-ionized water is clear to slightly hazy and virtually particulate-free.

PACKAGING

Standard package size is 10kg. Smaller sample sizes for evaluation are available.

STORAGE RECOMMENDATIONS

Store sealed in a cool, dry environment for 3 years, and up to 5 years with re-qualification.

ORDERING INFORMATION

Please order by product name "Bovine Serum Albumin Reagent Grade, Fatty Acid Free Powder" and refer to SKU # 69700. Proliant New Zealand Limited

27-33 Kawakawa Road, Feilding, 4775, NEW ZEALAND PO Box 366, Feilding, 4740, NEW ZEALAND. Phone: 64 6 280 4150. www.proliantinc.com

*Proliant's unique "Closed Loop" Manufacturing means that we collect only in exclusive abattoirs with our own approved proprietary collection system. The material undergoes ante-and post-mortem inspection to ensure it is the highest edible grade before it is shipped to our manufacturing facility. No other manufacturer can claim this important closed link, as they must buy their raw material from outside sources and the spot market.

What's more, from the time our product enters our tanks to the moment it is loaded into the dryers, the product is not exposed to the external environment. Once the raw material reaches our cGMP plant, the material is loaded directly into our process and manufactured through a series of closed tanks, lines, filters and separation equipment. In our plant, there are no exposed filter presses or open tanks, nor is any nonfood grade or noxious solvent material introduced into the process. There is also no possibility of contamination with other animal-derived products or bovine tissues in our completely dedicated facility.

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Date Prepared: Date of Manufacture: Date of Expiry: Product Description: 28, February, 2019 11, October, 2017 10, October, 2022 Bovine Serum Albumin Lyophilized Powder Reagent Grade Fatty Acid Free For Research or Further Manufacturing Use Only **NZ72840101** 69700

Specification

None Detected

None Detected

6.5-7.5/Ambient

6.5-7.5/Ambient

 $\leq 10 \text{ ppm}$

≤ 3 EU/mg

≤ 1,000 cfu/g

≤ 100 MPN/g

None Detected

None Detected

Absent/25g

Clear to slightly hazy.

Yellow to yellow-green

≥ 98.0%

≥ 98.0%

≤ 5.0%

< 0.01%

< 2%

Certificate of Analysis

Product Descrip

SKU #: Analysis:

Analyte Purity Protein (Dry Basis) Moisture Ash BlgG NEFA

Solubility

Protease

- pH (10% Solution)/Temp pH (1% Solution)/Temp Heavy Metals (Pb) Endotoxin APC Total Coliforms MPN Salmonella
- E. coli by MPN ≤ 10 MPN/g Asepsis None Detected BVD Virus None Detected Mycoplasma None Detected

Pathogen Inducing Cytopathy Pathogen Inducing Haemadsorption

K Muggeridge Quality Department

<u>18-Feb-2019</u> Date

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Result	Method	
100.0%		
101.3%	Agarose Gel	
	By calculation	
1.7%	AOAC 930.15	
0.9%	AOAC 923.03	
Complies	Turbidimetric Analysis	
Complies	Enzymatic Assay	
Pass	4% Solution in H ₂ 0 (visual	
None Detected	clarity) Enzymatic Assay (Detection limit 0.005 units/mg)	
7.0	10% Solution in H ₂ 0	
6.9	1% Solution in NaCl	
< 1 ppm	AOAC 984.27 (Modified)	
< 0.01 EU/mg	LAL	
< 10 cfu/g	AOAC 990.12	
< 3 MPN/g	USFDA-BAM	
Absent	PCR-Salmonella by	
	GeneScan	
< 3 MPN/g	USFDA-BAM	
None Detected	Culture	
None Detected	Virus Isolation	
None Detected	Culture	
None Detected	Virus Isolation	
None Detected	Virus Isolation	