

Bovine Serum Albumin
Precision Grade Powder
Manufactured in New Zealand

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, minimizes analytes 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 Source Precision Grade Bovine Serum Albumin product is an ideal choice for diagnostic and research applications where enhanced sensitivity is required due to low NEFA and high Monomer specifications.

APPLICATIONS

- Protease-sensitive Immunoassays such as RIA, EIA, Fluorescent and Chemiluminescent
- Protein Standard, Diluent
- Protein, Conjugate or Enzyme Stabilizer
- Hybridization
- Selected Cell Culture applications

FEATURES / BENEFITS

- High Purity, Low Interference, Low Background
- Low Fatty Acid Content
- High Monomer Content
- Virtually No Detectable Protease Activity, Ensures Assay Integrity
- "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

SCIENTIFIC ANALYSIS

	<u>Specification</u>	<u>Typical Values</u>
Protein (dry basis)	≥ 96.0%	99%
Purity (albumin)	≥ 98%	100%
Fatty Acids (NEFA)	≤ 0.05%	None Detected
Monomer	≥ 85%	92%
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%	<2%
Protease	≤ 0.005 Units/mg	None Detected
Endotoxin	≤ 3 EU/mg	0.1 EU/mg
IgG	None Detected	None Detected

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 below -15 deg C for 4 years, and up to 5 years with re-qualification.

ORDERING INFORMATION

Please order by product name "Bovine Serum Albumin, New Zealand Precision Grade Lyophilized Powder" and refer to SKU # 69750. 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 non-food 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.

Certificate of Analysis

Date of Manufacture: 11 February 2019
 Date of Expiry: 10 February 2024
 Product Description: Bovine Serum Albumin Lyophilized Powder
 Precision Grade, Fatty Acid Free
 Lot Number: **NZ90420101**
 SKU: 69760

Analysis:

<u>Analyte</u>	<u>Specification</u>	<u>Result</u>	<u>Method</u>
Purity	≥ 98.0%	100.0%	Agarose Gel
Protein (Dry Basis)	≥ 98.0%	102.2%	By calculation
Moisture	≤ 5.0%	2.8%	AOAC 930.15
Ash	< 2%	0.3%	AOAC 923.03
BlgG	None Detected	Complies	Turbidimetric Analysis
NEFA	≤ 0.01%	Complies	Enzymatic Assay
Solubility	Clear to slightly hazy Yellow to yellow-green	Pass	4% Solution in H ₂ O (visual clarity)
Protease	None Detected	None Detected	Enzymatic Assay (Detection limit 0.005 units/mg)
pH (10% Solution)/Temp	6.5-7.5	6.9	10% Solution in H ₂ O
pH (1% Solution)/Temp	6.5-7.5	7.0	1% Solution in NaCl
Heavy Metals (Pb)	≤ 10 ppm	< 1 ppm	AOAC 984.27 (Modified)
Endotoxin	≤ 3 EU/mg	< 0.01 EU/mg	LAL
APC	≤ 1,000 cfu/g	< 10 cfu/g	AOAC 990.12
Total Coliforms MPN	≤ 100 MPN/g	< 3 MPN/g	USFDA-BAM
Salmonella	Absent/25g	Absent	BACGene
E. coli by MPN	≤ 10 MPN/g	< 3 MPN/g	USFDA-BAM
Asepsis	None Detected	None Detected	Culture
BVD Virus	None Detected	None Detected	Virus Isolation
Mycoplasma	None Detected	None Detected	Culture
Pathogen Inducing Cytopathy	None Detected	None Detected	Virus Isolation
Pathogen Inducing Haemadsorption	None Detected	None Detected	Virus Isolation



K Muggeridge
Quality Department

29-Oct-2019

Date