

Immuno-gG[®] SBI

Purified Dairy-Free Source of Immunoglobulins

Immuno-gG[®] SBI is a dairy-free immunoglobulin concentrate formula designed to support healthy digestion and immune function. This purified source of immunoglobulin G (IgG) is derived from bovine serum, making it free of lactose, casein and β -lactoglobulins.

Life Begins in the Gut

The digestive system is the foundation of getting and staying healthy. Although there are many benefits to a digestive system running optimally, some key advantages include a healthy immune system and the protection against harmful bacteria, viruses, yeast and fungus.

Immunoglobulins play an important role in both the support of healthy digestion and immune function. They are proteins that function as antibodies to neutralize and eliminate unwanted toxins like lipopolysaccharide (LPS) before they have a chance to activate the immune system or induce inflammation.

Mechanism of Action

The method by which immunoglobulins and other bioactive peptides found in serum-derived bovine immunoglobulins (SBI) help to maintain gut barrier function is believed to involve the direct binding of microbial components found naturally in the digestive tract. *In vitro* studies have demonstrated that SBI binds to many potentially toxic microbial antigens that appear normally in the intestinal tract (see list of microbial components proven to bind to SBI in Table 1). Immunoglobulins bind microbes and toxins in the GI tract and eliminate them prior to immune system activation.



These microbial antigens (e.g., bacterial endotoxin) that are present in the intestinal tract due to the normal breakdown and turnover of resident bacteria and/or result from the consumption of contaminated food or water have the potential to activate the intestinal immune system. By binding to these microbial antigens (Table 1), SBI helps to create a complex so large that it has difficulty penetrating the intestinal epithelium, allowing instead for the antigenic complex to remain in the intestinal lumen and exit the intestinal tract following normal peristalsis.

To demonstrate this action, Detzel, et al.¹ conducted a study using an *in vitro* cell culture model to show that binding of antigens by the immunoglobulins in SBI prevented translocation of the antigens across epithelial cells, which in turn avoided the production of inflammatory cytokines by adjacent immune cells. These results suggest that the binding action of immunoglobulins in SBI helps keep toxic antigens within the lumen of the intestinal tract and avoid their absorption into the blood stream, which may help manage gut permeability and immune activation that occur with exposure to such antigens.¹ By binding to microbes and toxins, **Immuno-gG[®] SBI** enhances microbiome balance and facilitates gut barrier strength, resetting immune tolerance.*



(800) 231-5777

6801 Biotics Research Drive • Rosenberg, TX 77471
biotics@bioticsresearch.com • www.bioticsresearch.com

Table 1: ImmunoLin® binds a variety of bacterial antigens

SBI Binding Component		Description
Bacterial Antigen	Lipopolysaccharide (LPS)	Major immune activating cell wall component (lipid & carbohydrate)
	Flagellin	Antigenic proteins that form appendages to provide motility
	Lipoteichoic acid (LTA)	Immunostimulatory cell wall component of Gram (+) bacteria
	PAM3CSK4	Immunostimulatory bacteria lipopeptide (synthetic)
	Poly I:C	Analog of double-stranded RNA; stimulates cytokine production
	Cytosine-p-guanine dinucleotides (CpG)	Bacterial DNA motif
	C. difficile toxins A & B	Virulence factors
Whole Bacteria (lysate)	Helicobacter pylori	Gram (-) bacteria found in the stomach
	Listeria monocytogenes	Gram (+) anaerobic bacteria
	Mycoplasma spp.	Bacteria lacking cell wall; resistant to most antibiotics

Four Reasons Serum-Derived Bovine Immunoglobulins are a Superior Alternative to Bovine Colostrum

1. **Immuno-gG® SBI** is lactose-free. Colostrum is a milk-based compound, thus products containing it include elevated levels of lactose (a sugar present in milk that is known to be poorly tolerated, often resulting in GI distress for certain portions of the general population).
2. **Immuno-gG® SBI** provides a higher concentration of immunoglobulins vs colostrum and the highest protein content and the highest percentage of immunoglobulins [specifically immunoglobulin-G (IgG)] available compared to other commercially available colostrum supplements (Table 2). The higher IgG concentration makes **Immuno-gG® SBI** a more potent source of immunoglobulins.
3. **Immuno-gG® SBI** is the purest source of IgG available, containing extremely low levels of endotoxin contamination vs colostrum. Due to the nature of the product and its collection method, bovine colostrum is often contaminated with elevated levels of endotoxin. Once ingested, these endotoxins are exposed to the intestinal mucosa, potentially initiating a harmful inflammatory response that is often associated with increased gut permeability² and GI distress.

4. Bovine serum immunoglobulins are more stable and predictable than colostrum. For 15 years, over 2000 production lots have been manufactured utilizing the same rigorous isolation, purification and filtration methods. These methods are deployed in a cGMP facility that employs extensive precautions and procedures to ensure the safety, cleanliness, stability and consistency of each batch. In contrast, the quality and consistency of the preparations of bovine colostrum utilized in dietary supplements can vary based upon the following variables:

- the cow's disease and breeding history³
- the collection time post-calving⁴
- the volume and method of collection utilized to avoid bacterial contamination⁵
- the length of time collected material remains in storage prior to processing.

The factors outlined above may partly explain the inconsistencies observed in the results from clinical studies conducted with colostrum supplements.⁶ In summary, while bovine colostrum is well-researched and proven in multiple commercial product formulations, evidence from composition studies indicates that in a head-to-head comparison, serum-derived immunoglobulins are the superior alternative for digestive health and immune support dietary supplement applications.

Table 2: Comparison of ABI and Representative Colostrum Products

	SBI	Colostrum Product #1^A	Colostrum Product #2^B
Product Description	Serum-Derived immunoglobulin/Protein Isolate (SBI)	Immunoglobulin Concentrate from Colostral Whey Peptides	Highly Concentrated Colostrum IgG
No. lots tested	3	3	2
% Protein	90.6 ± 1.1	72.4 ± 3.7	74.1 ± 0.9
% IgG	52.4 ± 0.7	31.5 ± 2.9	35.3 ± 3.5
% Lactose	Below LD^B	8.1 ± 1.9	8.3 ± 0.7
Endotoxin (EU/mg)	0.3 ± 0.1	2.4 ± 0.5	1.8 ± 0.7

^ANames of products tested are available upon request.

^BLD, limit of detection. The lactose content of SBI is typically below the limit of assay detection (0.15%) since SBI is purified from plasma which does not contain lactose.

Over 40 Human Clinical Trials and Studies

ImmunoLin[®] is a branded ingredient with over 40 human studies demonstrating its clinical efficacy in digestive and immune health.⁷⁻¹⁶ In an open-label human clinical study, GI-challenged patients showed positive outcomes in several areas, including inflammatory balance, gut barrier function and immune cell counts.^{17,18,19} Subjects were given 2.5 g serum-derived bovine immunoglobulins twice daily, which resulted in increased CD4+ counts in the duodenum after eight weeks, indicating a regenerative effect on the tissue and immune function in the intestines.

Purest IgG on the Market

Immuno-gG[®] SBI contains ImmunoLin[®], a purified protein-based (>90%) source of serum-derived bovine immunoglobulin/protein isolate (SBI) that is manufactured using a tightly controlled and highly reproducible process at an FDA-inspected facility. By using vertically integrated closed-loop processing, all points of the supply chain are tightly controlled, which results in the cleanest IgG on the market.

Immuno-gG[®] SBI contains 2.42 mg of ImmunoLin[®]. As a result, this product helps to strengthen gut barrier health and integrity, support a healthy immune system and maintain normal inflammatory balance.*

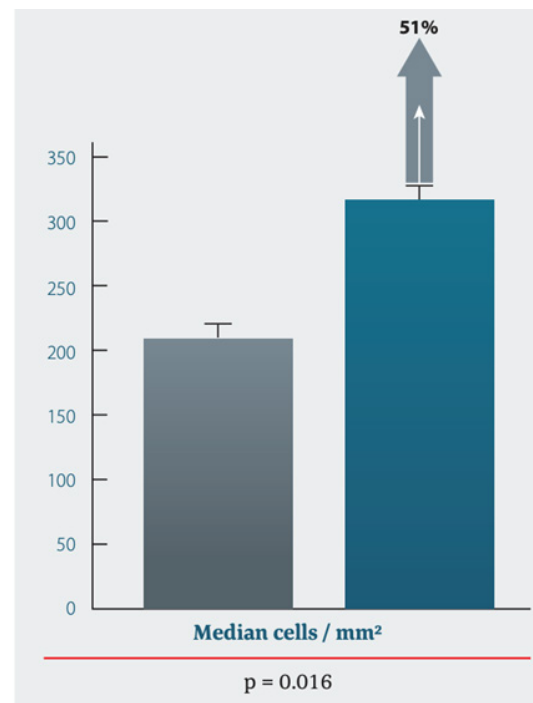


Figure 1: Duodenal GALT Immune Reconstitution with SBI^{17,18,19}

Key Benefits*:

- Enhances mucosal immunity
- Supports GI barrier health and integrity
- Helps maintain normal inflammatory balance

References

1. Detzel CJ, Horgan A, Henderson AL, Petschow BW, Warner CD, Maas KJ, et al. Bovine immunoglobulin/protein isolate binds pro-inflammatory bacterial compounds and prevents immune activation in an intestinal co-culture model. *PLoS One*. 2015;10(4):e0120278.
2. Fritscher-Ravens A, Schuppan D, Ellrichmann M, Schoch S, Rocken C, Brasch J, et al. Confocal endomicroscopy shows food-associated changes in the intestinal mucosa of patients with irritable bowel syndrome. *Gastroenterology*. 2014;147(5):1012-20 e4.
3. A Guide to Colostrum and Colostrum Management for Dairy Calves. 2001 [Available from: https://www.aphis.usda.gov/animal_health/naahms/dairy/downloads/bamn/BAMN01_Colostrum.pdf].
4. Moore M, Tyler JW, Chigerwe M, Dawes ME, Middleton JR. Effect of delayed colostrum collection on colostrum IgG concentration in dairy cows. *Journal of the American Veterinary Medical Association*. 2005;226(8):1375-7.
5. Stewart S, Godden S, Bey R, Rapnicki P, Fetrow J, Farnsworth R, et al. Preventing bacterial contamination and proliferation during the harvest, storage, and feeding of fresh bovine colostrum. *Journal of dairy science*. 2005;88(7):2571-8.
6. Colostrum - Scientific review on usage, dosage, side effects. [Available from: <https://examine.com/supplements/colostrum/>].
7. Bateman et al. Serum-derived bovine immunoglobulin/protein isolate in the alleviation of chemotherapy-induced mucositis. *Support Care Cancer*. 17 June 2015.
8. Aminah Jatoi. Anti-inflammatory therapy: exploring exercise, serum-derived bovine immunoglobulin/protein isolates, and ruxolitinib for cancer-associated weight loss syndrome. *Curr Opin Support Palliat Care*. Volume 7, No 4. December 2013.
9. Gerald L Klein, Bryon W Petschow, Audrey L Shaw, Eric Weaver. Gut barrier dysfunction and microbial translocation in cancer cachexia: a new therapeutic target. *Curr Opin Support Palliat Care*. Volume 7, No 4. December 2013.
10. Larry Good, Raymond Panas. P-003 Remission of Pouchitis in Patients Following Serum-Derived Bovine Immunoglobulin/Protein Isolate (SBI) Therapy. *Inflammatory Bowel Diseases*. March 2016.
11. Ira Shafraan, Patricia Burgunder, David Wei, Hayley E. Young, Gerald Klein and Bruce P. Burnett. Management of inflammatory bowel disease with oral serum-derived bovine immunoglobulin. *Therapeutic Advances in Gastroenterology*. July 10, 2015.
12. Rachelle A Soriano, Asuncion G Ramos-Soriano. Clinical and Pathologic Remission of Pediatric Ulcerative Colitis with Serum-Derived Bovine Immunoglobulin Added to the Standard Treatment Regimen. *Case Reports in Gastroenterology*. 2017.
13. Larry Good and Raymond Panas. Case Series Investigating the Clinical Practice Experience of Serum-Derived Bovine Immunoglobulin/Protein Isolate (SBI) in the Clinical Management of Patients with Inflammatory Bowel Disease. *Journal of Gastrointestinal & Digestive System*. 2015, 5:2.
14. BP Burnett, 247 Oral Serum-Derived Bovine Immunoglobulin Therapy to Help Achieve Clinical Remission with Associated Decreases in Fecal Calprotectin in a Pediatric Ulcerative Colitis Patient. *North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. Annual Meeting Washington Hilton, Washington DC, October 7-11, 2015.*
15. Brian D. Beauerle, Bruce P. Burneet and Gerald W. Dryden. Successful management of refractory ulcerative colitis with orally administered serum-derived bovine immunoglobulin therapy. *Clinical Case Report Review, School of Medicine-University of Louisville, Louisville, KY, 2015.*
16. Amir Awad and Victoria S. Jason. Use of a Nutritional Therapy, Serum-Derived Bovine Immunoglobulin/Protein Isolate (SBI), to Achieve Improvement in Two Different Cases. *Journal of Gastrointestinal & Digestive System*. April 10, 2015.
17. Asmuth DM, Ma ZM, Albanese A, Sandler NG, Devaraj S, Knight TH, et al. Oral Serum-Derived Bovine Immunoglobulin Improves Duodenal Immune Reconstitution and Absorption Function in Patients with HIV Enteropathy. *Aids*. 2013;27:2207-17.
18. Asmuth, DM, Somsouk M, Hunt PJ, Ma ZM, Miller CL, XD Hinkle J, et al. Serum-Derived Bovine Immunoglobulin Protein Isolate Increases Peripheral and Mucosal CD4+ T-cell counts in Patients with HIV Enteropathy. 8th IAS Conference on HIV Pathogenesis, Treatment and Prevention (AIDS, 2015); MOAA02; Vancouver, Canada 19-22 July.
19. Bosi P, Casini L, Finamore A, Cremoklini C, Meriardi G, Trevisi P, et al. Spray-dried plasma improves growth performance and reduces inflammatory status of weaned pigs challenged with enterotoxigenic *Escherichia coli* K88. *Journal of Animal Science*. 2004;82(6):1764-72.



Immuno-gG® SBI
120 capsule bottle (#5292)

Supplement Facts

Serving Size: 4 Capsules
Servings Per Container: 30

	Amount Per Serving	% Daily Value
Calories	10	
Protein	2 g	4%†
Serum-Derived Bovine Immunoglobulin Concentrate (ImmunoLin®)		
Immunoglobulin G (IgG)	1.15 g	*

† Percent Daily Values are based on a 2,000 calorie diet.
* Daily Value not established

Other ingredients: Capsule shell (gelatin and water) and sunflower lecithin.
This product is dairy, gluten and GMO free.

ImmunoLin® is a registered trademark of Entera Health, Inc.

RECOMMENDATION: Four (4) capsules each day as a dietary supplement or as otherwise directed by a healthcare professional.

KEEP OUT OF REACH OF CHILDREN

Store in a cool, dry area. Sealed with an imprinted safety seal for your protection.

Product #5292 Rev. 09/20



Immuno-gG® SBI Powder
2.6 ounce jar (#5293)

Supplement Facts

Serving Size: 2.5 g (approx. 1 scoop)
Servings Per Container: 30

	Amount Per Serving	% Daily Value
Calories	10	
Protein	2 g	4%†
Serum-Derived Bovine Immunoglobulin Concentrate (ImmunoLin®)		
Immunoglobulin G (IgG)	1.2 g	*

† Percent Daily Values are based on a 2,000 calorie diet.
* Daily Value not established

Other ingredients: Sunflower lecithin.

This product is dairy, gluten and GMO free.

ImmunoLin® is a registered trademark of Entera Health, Inc.

RECOMMENDATION: One scoop of Immuno-gG® SBI Powder each day or as otherwise directed by a healthcare professional.

KEEP OUT OF REACH OF CHILDREN

Store in a cool, dry area. Sealed with an imprinted safety seal for your protection.

Product #5293 Rev. 09/21



(800) 231-5777

6801 Biotics Research Drive • Rosenberg, TX 77471
biotics@bioticsresearch.com • www.bioticsresearch.com