

IS50™ Fiber Blend: Background and Substantiation

What is dietary fiber?

Dietary fiber is defined as the non-digestible carbohydrates that occur naturally in plants. Functional fibers are isolated non-digestible carbohydrates that have been shown to exert beneficial physiological effects in humans. For healthy adults, the Institute of Medicine recommends a daily fiber intake of 14 g per 1000 calories.¹

What is the role of fiber in clinical nutrition?

Diarrhea and constipation are common complaints among patients on fiber-free enteral formulas.^{2,3} Fiber has been shown to normalize defecation frequency, consistency, and transit time,⁴ and may be added to enteral formulas to promote regularity.

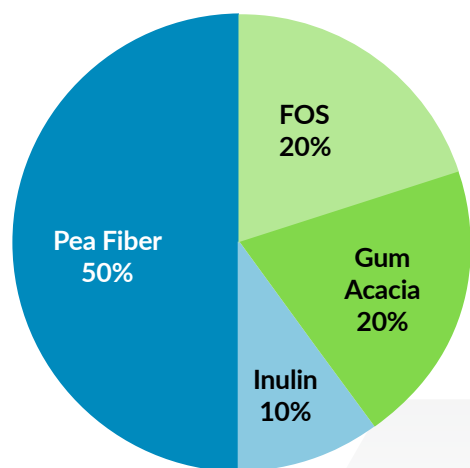
The European Society for Clinical Nutrition and Metabolism (ESPEN) provides the following information on the use of fiber-containing enteral formulas:⁵

- A fiber intake of 15-30 g/day is advisable for patients on enteral nutrition.
- In non-ICU patients or those requiring long-term enteral nutrition, a mixture of bulking and fermentable (insoluble and soluble) fiber is the best approach.
- Dietary fiber can contribute to normalization of bowel function in elderly patients.

While fiber is not recommended for critically ill patients at high risk for bowel ischemia or severe dysmotility, soluble fiber may be beneficial for fully resuscitated, hemodynamically stable critically ill patients.⁶ A fiber blend may be beneficial for stable patients who are not critically ill and who may be transitioning from the ICU.

What is IS50™?

IS50™ is a proprietary blend containing **50% Insoluble** fiber (pea fiber) and **50% Soluble** fiber (made up of 40% fructooligosaccharides (FOS), 20% inulin, and 40% gum acacia). This blend has been researched in a series of human and in vitro studies.



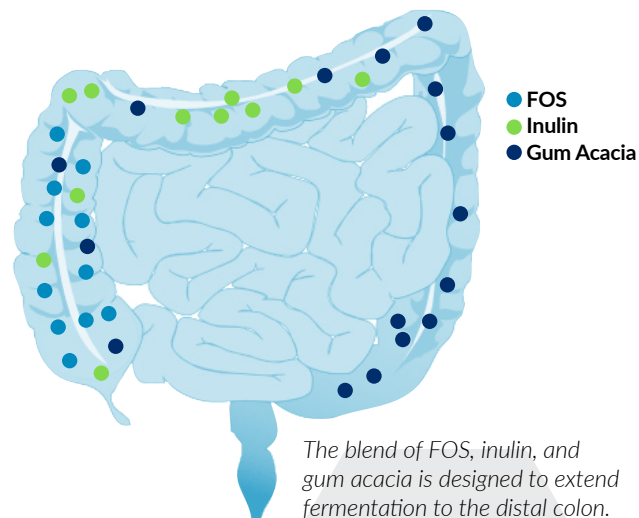
IS50™ is the fiber blend used across the Nestlé Health Science adult standard fiber-containing tube feeding formulas. FIBERSOURCE® HN, ISOSOURCE® 1.5 CAL, NUTREN® 1.0 FIBER, and REPLETE® FIBER each contain 15.2 g of IS50™ per liter.

Why IS50™?

Different fiber sources exert varying physiological effects in the body. Fiber blends are thought to be advantageous over fiber from a single source as the combination of different fibers allows achievement of a range of physiological effects and may result in better tolerance.⁷

IS50™ was designed to leverage benefits of both insoluble and soluble fibers:

- Insoluble: pea fiber is minimally fermented and contributes to fecal bulk.
- Soluble: blend of short (FOS), medium (inulin), and long chain (gum acacia) fibers. These fibers are fermented at different rates to provide benefits of fermentation throughout the colon.^{8,9}



In support of IS50™ two human studies have been published:^{10,11}





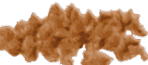

de Luis et al¹⁰ evaluated tolerance of a formula containing 15 g/L IS50™ (ISOSOURCE® Protein Fibre, used outside the US) in an open-label, non-randomized, descriptive study of 18 patients requiring full enteral feeding for >7 days. They found:

- The formula was well tolerated with a very low frequency of gastrointestinal symptoms.
- Investigator assessment of tolerance was normal in 100% of cases.
- There was a statistically significant increase in the daily number of bowel movements, from less than 1 every other day at the start of the study to approximately 1 per day at the final visit (0.44 v. 0.89; p=0.035).¹⁰ This increase was not associated with diarrhea, and suggests a positive effect on the regulation of intestinal transit.

Koecher et al¹¹ compared bowel function and tolerance in 20 healthy subjects consuming an enteral formula with or without 15 g/L IS50™ for 2 weeks in a crossover design. Compared to the fiber-free formula, consumption of IS50™ resulted in:

OUTCOME	MEASURE
Stool bulking	• 38% higher mean fecal weight (p=0.0321)
Improved stool consistency	• Reduced fecal moisture (p<0.0001) • Improved Bristol Stool Scale score (p<0.0001)
Beneficial effects on gut health	• Greater number of fecal bifidobacteria (p<0.05) • Increased fecal Short Chain Fatty Acids (SCFA) (p=0.029) ⁹
Good tolerance	• Reduced incidence of symptoms related to bowel urgency/uncontrolled stools (p<0.02) • No difference in gas and bloating symptoms between the formula with IS50™ and habitual diet ⁹

Overall, consumption of IS50™ had a normalizing effect on bowel function. The fibers had a bulking effect and fecal moisture content was more similar to stools on a habitual diet (data not shown). This was further evidenced by Bristol Stool Scale scores which improved from 5.12 to 4.15. Values were lower with IS50™, indicative of a more normal, formed stool as compared to the fiber-free formula.

BRISTOL STOOL SCALE		
	TYPE	DESCRIPTION
	1	Separate hard lumps
	2	Lumpy and sausage like
	3	A sausage shape with cracks in surface
	4	Like a smooth, soft sausage or snake
	5	Soft blobs with clear cut edges
	6	Mushy consistency with ragged edges
	7	Liquid consistency with no solid pieces

IS50™: 4.15
Fiber-Free: 5.12

In vitro studies also support a beneficial fermentation profile for the soluble fiber blend in IS50™.^{8,9} The soluble fiber blend was shown to:

- Increase production of SCFAs, including butyrate.⁹ SCFAs help regulate absorption of water and electrolytes, and butyrate acts as a major energy source for colonic epithelial cells.¹²
- Extend benefits of fermentation (e.g. reduced pH) to the distal colon. In contrast, blends containing only shorter chain fibers are fermented primarily in the proximal colon.⁹
- Promote growth of beneficial bacteria (bifidobacteria and lactobacilli).⁹

How long have Nestlé Health Science formulas with IS50™ been available?

Enteral formulas containing IS50™ were first launched in 2011 in Europe in a range of tube feeding formulas (ISOSOURCE® STANDARD FIBRE, ISOSOURCE® PROTEIN FIBRE, ISOSOURCE® ENERGY FIBRE, and ISOSOURCE® MIX). In 2014, over 1.5 million cases of formula containing IS50™ were sold in Europe. In the last 4 years, there have been no major concerns regarding tolerance. Use of IS50™ in over 1,000 homecare patients in Switzerland and Germany did not yield any negative feedback.*

What should be expected when transitioning to a formula containing IS50™?

When switching tube feeding formulas, it is not uncommon for individuals to experience some issues related to tolerance. For those on long term tube feedings, the GI tract becomes acclimated to a specific formula and an adjustment period may be required. This may be similar to the tolerance issues that can be expected when enteral nutrition is first initiated or when infusion rates are changed. Just as a gradual approach is recommended for transitioning from parenteral nutrition to enteral nutrition or from enteral nutrition to an oral diet, a similar approach is also advisable for transitioning from one formula to another. When possible, it may be helpful to gradually switch formulas by introducing the new formula one carton or feeding at a time over several days. Tolerance issues such as distension, nausea, bloating and discomfort, and changes in stool frequency and consistency may occur during the transition period.¹³⁻¹⁵ As the GI tract adapts, these changes are likely to resolve within a few days.

Summary

Fiber is a key component of a healthy diet and a blend of insoluble and soluble fibers support bowel management and GI health.⁴ Tube feeding formulas containing IS50™ have been available for nearly 4 years, and good tolerance has been demonstrated in studies of patients and healthy adults.^{10,11} The addition of IS50™ to Nestlé Health Science adult standard tube feeding formulas may prove beneficial for those patients who are receiving enteral nutrition and who require a fiber-containing formula. IS50™ fiber blend may be particularly beneficial for those who require long-term tube feeding, as fiber can help to promote bowel regularity and gut health.⁴

*Internal communication, data on file with Nestlé Health Science

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