

Summary of Clinical Tolerance Studies Conducted with Isomalto-oligosaccharide (IMO) Products

Study Population and study design	Duration	Daily Dose Levels	Results	Reference
9 healthy males (~26 years old) and 29 females (~23 years old)	Single dose	10, 20, or 40 g	No GI disturbances.	Oku and Nakamura (2003)
81 healthy males and 119 females (~30 years old) (8 ingested IMO mix); double-blind placebo-controlled study	7-day run-in and 7-day treatment period	0 (placebo) or 10 g/day (2 equal portions)	↑ (slight) in excess flatus, bloating, borborygmi, and abdominal pains (all mild symptoms) vs. run-in period; however, No Δ in any of the GI symptoms vs. placebo control; None of the subjects experienced diarrhea.	Bouhnik <i>et al.</i> (2004)
6 healthy males (26-48 years old)	10 days	20 g/day	None of the subjects experienced diarrhea; only transient increase in flatulence in 2/24 subjects.	Kohmoto <i>et al.</i> (1988)
18 older subjects (5 males and 13 females; 50-93 years old)	14 days			
20 healthy females and 11 males (22 subjects w/ history of constipation) (~27 – 30 years old)	21 days (total) ²	10 or 15 g	No GI disturbances. ↑ Defecation frequency in constipated subjects w/ 15 g IMO mix vs. 1 st week.	Kaneko <i>et al.</i> (1993)
8 male and 12 female hemodialysis patients (~64 years old)	14-day run-in and 28-day treatment period	30 g/day (2 equal portions)	↑ in severity of distension (10%) ¹ , tormina (10.5%), borgorgymi (6.1%), spasms (4.5%) and in bowel movements; No Δ in diarrhea (5%). <u>Clinical Chemistry</u> ↑ in Hb, Ht, and HDL-Ch vs. run-in; ↓ in Tg, Ch; No Δ in glucose, albumin, total protein; BUN, Cre, Ca ²⁺ , P, and LDL-Ch.	Wang <i>et al.</i> (2001)
7 elderly males w/ history of constipation (~75 years old)	30-day run-in and 30-day treatment period	↑ from 8 to 24 g (1 st 10 days)	↑ in defecation frequency and wet and dry fecal weight per day and stool sample; no reports of GI disturbances. <u>Clinical Chemistry</u> ↑ in Na ⁺ ; No Δ glucose, total protein, albumin, TG, Ch, HDL-Ch, Ca ²⁺ , P, and K vs. run-in.	Chen <i>et al.</i> (2001)

No Δ = No change; BUN = Blood urea nitrogen; Ca²⁺=Calcium; Cre=Cretinine; Ch=Cholesterol; GI=Gastrointestinal; HB=Hemoglobin; HDL-Ch=High-density lipoprotein cholesterol; Ht=Hematocrite; LDL-Ch=Low density lipoprotein cholesterol; K=Potassium; Na⁺=Sodium; P=Phosphorus; TG=Triglycerides.

¹ Percent in parentheses indicates percent of patients experiencing GI symptoms.

² 1st week run-in period; 2nd and 3rd week IMO mix ingestion; 4th week break; 5th week IMO mix ingestion.