

## Alternative lipid injectable emulsions (ILEs) for parenterally fed adult patients

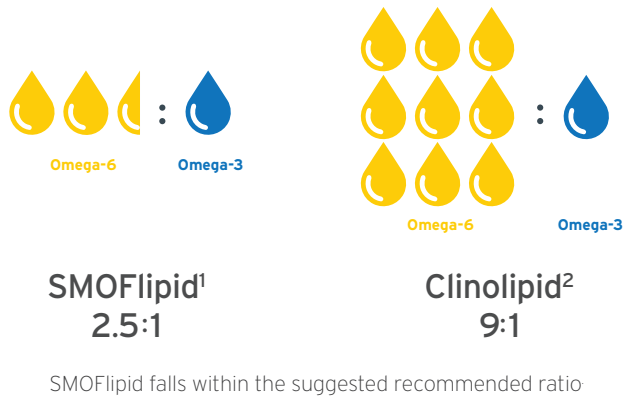
	<b>SMOFlipid®</b> Lipid Injectable Emulsion, USP 20% <sup>1</sup>	<b>Clinolipid®</b> 20% Lipid Injectable Emulsion, USP* <sup>2</sup>
Pediatric Indication (Including Term and Preterm Neonates)	✓	
Adult Indication	✓	✓
No Limitations of Use	✓	
<b>Composition</b>		
Expert Suggestion for Omega-6:Omega-3 Ratio (2:1 to 4:1)	✓	
Contains Soybean Oil	✓	✓
Contains Medium-chain Triglycerides (MCTs)	✓	
Contains Olive Oil	✓	✓
Contains Fish Oil that Includes the Omega-3 Fatty Acids EPA and DHA	✓	

\*Clinolipid is a registered trademark of Baxter International Inc.

# About lipid sources

## Omega-6:omega-3 fatty acid ratio

Expert recommendations suggest an optimal omega-6:omega-3 ratio of 2:1 to 4:1 in ILEs.<sup>3-6</sup>



Lipid Emulsion	Ratio of Omega-6:Omega-3 Fatty Acids
Recommendations <sup>3-6</sup>	2:1 to 4:1
1st-Generation Soybean Oil	7:1
2nd-Generation Clinolipid	9:1
SMOFlipid <sup>1</sup>	2.5:1

## Inflammatory profile per ASPEN guidance

### ASPEN Position Paper

"Based on substantial biochemical and clinical evidence, alternative oil-based IVFEs may have less proinflammatory effects, less immune suppression, and more antioxidant effects than the standard SO IVFEs and may potentially be a better alternative energy source."<sup>7</sup>







Graphic adapted from Vanek et al.<sup>7</sup>

## ASPEN ILE Safety Recommendations in Adults

"With the availability of other ILE products reducing the SO-ILE content, ILE may be provided to critically ill adults upon PN initiation without producing the inflammatory and immunosuppressive effects associated with SO-ILE. This approach would optimize the delivery of adequate energy and EFA without providing excessive amounts of dextrose. **To date, the optimal blend of oils for this population remains unknown, although a lower ratio of omega-6 and omega-3 FAs has been suggested.**"<sup>8</sup>

**Abbreviations:** EFA, essential fatty acid; FA, fatty acid; ILE, lipid injectable emulsion; IVFE, intravenous fat emulsion; PN, parenteral nutrition; SO, soybean oil.

# Lipid sources

			SMOFlipid <sup>1</sup>	Clinolipid <sup>2</sup>
Soybean oil		Provides EFAs.	30%	20%
MCT		A source of rapidly available energy. <sup>9</sup>	30%	-
Olive oil		Supplies monounsaturated FAs.	25%	80%
Fish oil		A source of EPA and DHA. <sup>10</sup>	15%	-

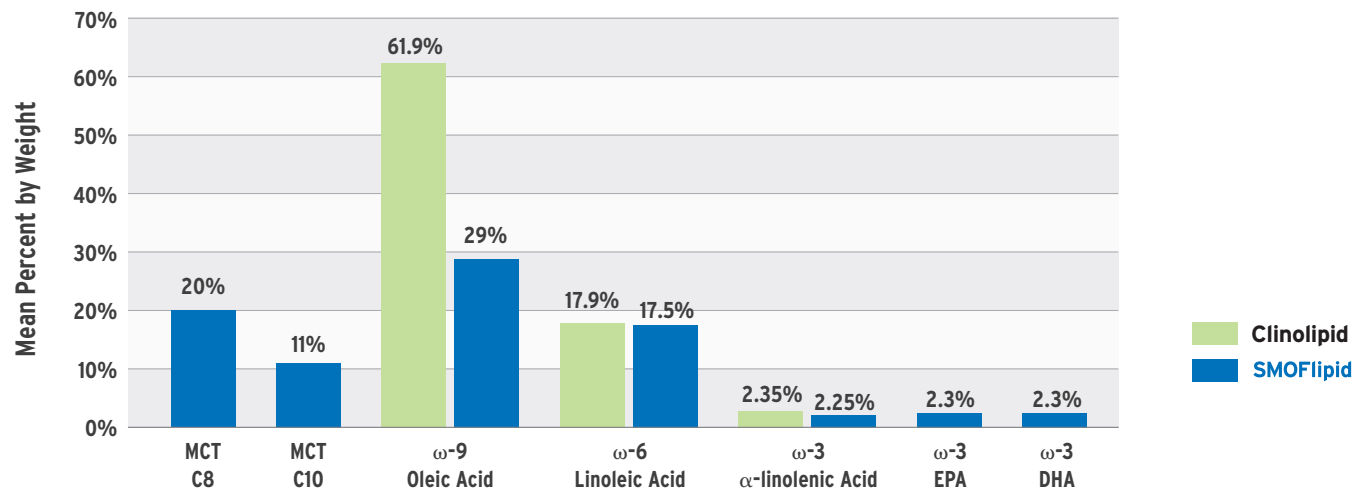
## ESPEN Guideline on Clinical Nutrition in the Intensive Care Unit

“Regarding the FA (fatty acid) composition of the lipid emulsions, the recent **expert recommendations indicated that a blend of FAs should be considered**, including medium-chain triglycerides (MCTs), omega-9 monounsaturated FAs, and omega-3 polyunsaturated FAs. At this stage, the evidence for omega-3 FA-enriched emulsions in non-surgical ICU patients is not sufficient to recommend it as a standalone.”<sup>11</sup>

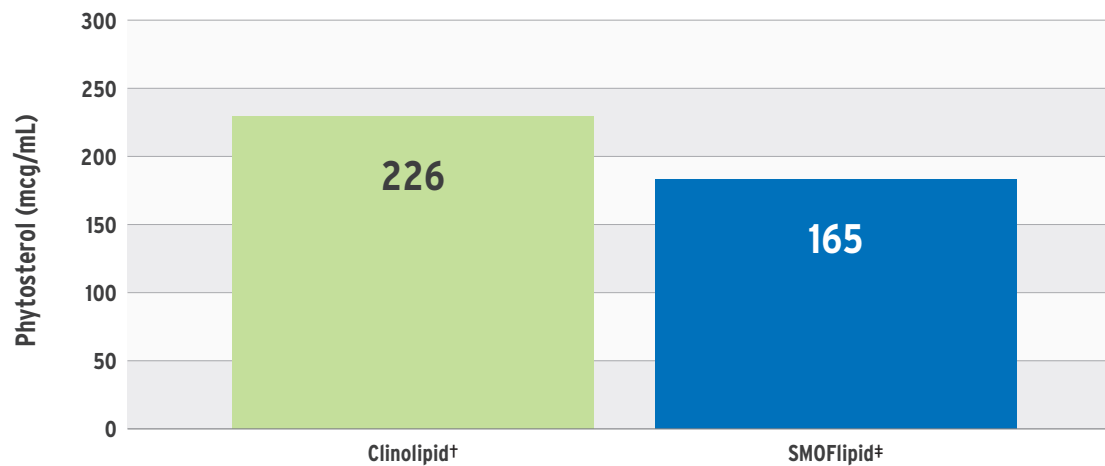
**Abbreviations:** DHA, docosahexaenoic acid; EPA, eicosapentaenoic acid.

# Composition comparison

## Fatty acid composition<sup>1,2</sup>



## Phytosterol content<sup>\*13</sup>



\*Data points are shown as mean values.

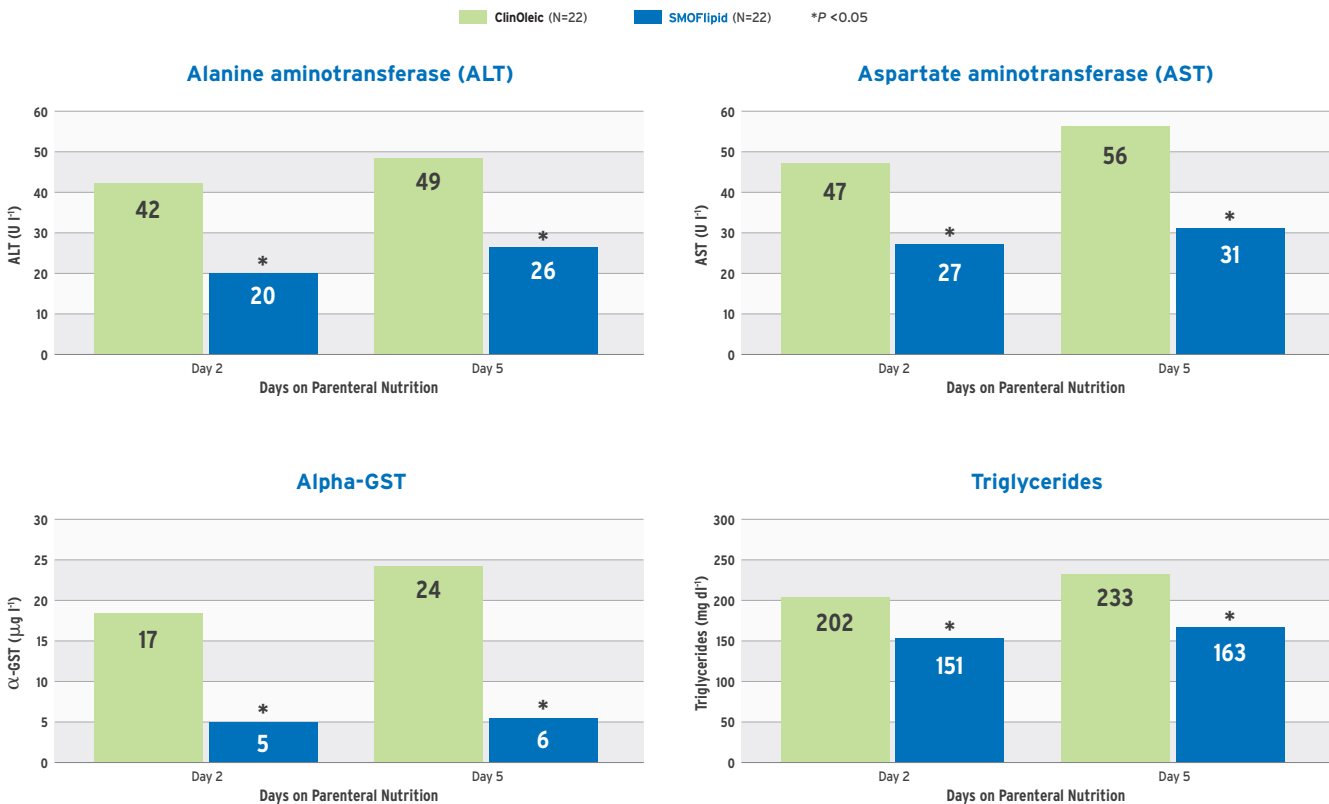
†The phytosterol range is  $226.83 \pm 6.42$  and  $274.38 \pm 2.60$ .<sup>13,14</sup>

‡The phytosterol range is  $165 \pm 10.4$ . Data on file.

# Clinical comparison

## SMOFlipid vs. ClinOleic® (sold as Clinolipid in the U.S.) in adults

In a prospective, randomized, double-blinded clinical trial, hepatic integrity was well retained with the administration of SMOFlipid.<sup>15</sup>



Adapted from Piper SN et al.<sup>15</sup>

Study dosage approximated at 1 g/kg/day; no significant difference at baseline; data points shown as mean values.

- Critically ill adult patients (N=44) from Germany and Switzerland requiring total PN<sup>15</sup>

**Abbreviations:** ALT, alanine aminotransferase; AST, aspartate aminotransferase; alpha-GST, alpha-glutathione s-transferase; TG, triglyceride.

# Comparing soybean oil ILE to alternative ILE

## Selected clinical study in intensive care patients\*



### SMOFlipid

- In a prospective, randomized, double-blinded, single center, French study of adult surgical ICU patients comparing soybean oil emulsion 20% (n=10) and SMOFlipid (n=10), SMOFlipid<sup>16</sup>:
  - Demonstrated no significant changes in triglyceride level while the soybean oil group showed a significant increase in triglyceride level ( $P < 0.01$ ) from baseline after 5 days
  - Company-sponsored studies showed that mean triglyceride levels from baseline values to week 4 were similar in both the SMOFlipid and comparator groups

\*This is not the only study for SMOFlipid compared with soybean oil lipid emulsions. The study described above is not intended to show superiority of one product over another.



## INDICATIONS AND USAGE

SMOFlipid is indicated in adult and pediatric patients, including term and preterm neonates, as a source of calories and essential fatty acids for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.

## IMPORTANT SAFETY INFORMATION

For intravenous infusion only into a central or peripheral vein. Use a non-vented non-DEHP 1.2 micron in-line filter set during administration. Recommended dosage depends on age, energy expenditure, clinical status, body weight, tolerance, ability to metabolize and eliminate lipids, and consideration of additional energy given to the patient. The recommended dose for adults and pediatrics is shown in Table 1. For information on age-appropriate infusion rate, see the full prescribing information. SMOFlipid Pharmacy Bulk Package is only indicated for use in pharmacy admixture programs for the preparation of three-in-one or total nutrition admixtures. Protect the admixed PN solution from light.

**Table 1: Recommended Adult and Pediatric Dosage**

Age	Nutritional Requirements	
	Initial Recommended Dosage	Maximum Dosage
Birth to 2 years of age (including preterm and term neonates)	0.5 to 1 g/kg/day	3 g/kg/day
Pediatric patients 2 to <12 years of age	1 to 2 g/kg/day	3 g/kg/day
Pediatric patients 12 to 17 years of age	1 g/kg/day	2.5 g/kg/day
Adults	1 to 2 g/kg/day	2.5 g/kg/day

SMOFlipid is contraindicated in patients with known hypersensitivity to fish, egg, soybean, peanut, or any of the active or inactive ingredients, and severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglycerides >1,000 mg/dL).

### Clinical Decompensation with Rapid Infusion of Intravenous Lipid Emulsion in Neonates and Infants:

Acute respiratory distress, metabolic acidosis, and death after rapid infusion of intravenous lipid emulsions have been reported.

### Parenteral Nutrition-Associated Liver Disease:

Increased risk in patients who received parenteral nutrition for greater than 2 weeks, especially preterm neonates. Monitor liver tests; if abnormalities occur consider discontinuation or dosage reduction.

Hypersensitivity Reactions: Monitor for signs or symptoms. Discontinue infusion if reactions occur.

Risk of Infections, Fat Overload Syndrome, Refeeding Syndrome, Hypertriglyceridemia, and Essential Fatty Acid Deficiency: Monitor for signs and symptoms; monitor laboratory parameters.

Aluminum Toxicity: Increased risk in patients with renal impairment, including preterm neonates.

Most common adverse drug reactions ( $\geq 5\%$ ) from clinical trials in adults were nausea, vomiting, and hyperglycemia. Most common adverse drug reactions ( $\geq 5\%$ ) from clinical trials in pediatric patients were anemia, vomiting, increased gamma-glutamyltransferase, and nosocomial infection.

**To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**This Important Safety Information does not include all the information needed to use SMOFlipid safely and effectively. Please see full prescribing information, for intravenous use at [www.freseniuskabinutrition.com/SMOFlipidPI](http://www.freseniuskabinutrition.com/SMOFlipidPI)**

Learn more about our full portfolio of innovations that nourish at  
**FreseniusKabiNutrition.com.**

**References:** **1.** SMOFlipid Prescribing Information, Fresenius Kabi USA, LLC. 2023. **2.** Clinolipid Prescribing Information, Baxter Healthcare Corporation. 2021. **3.** Grimble RH. *Clin Nutr Suppl.* 2005;1(3):9-15. **4.** Waitzberg DL, Torrinhas RS, Jacintho TM. *JPEN J Parenter Enteral Nutr.* 2006;30(4):351-367. **5.** Mayer K, Schaefer MB, Seeger W. *Curr Opin Clin Nutr Metab Care.* 2006;9(2):140-148. **6.** Grimm H, Mertes N, Goeters C, et al. *Eur J Nutr.* 2006;45(1):55-60. **7.** Vanek VW, Seidner DL, Allen P, et al. *Nutr Clin Pract.* 2012;27(2):150-192. **8.** Mirtallo JM, Ayers P, Boullata J, et al. *Nutr Clin Pract.* 2020;35(5):769-782. **9.** Deckelbaum RJ, Hamilton JA, Moser A, et al. *Biochemistry.* 1990;29(5):1136-1142. **10.** Kalish BT, Fallon EM, Puder M. *JPEN J Parenter Enteral Nutr.* 2012;36(4):380-388. **11.** Singer P, Blaser AR, Berger MM, et al. *Clin Nutr.* 2019;38(1):48-79. **12.** Martindale RG, Berlanda D, Boullata JI, et al. *JPEN J Parenter Enteral Nutr.* 2020;44 Suppl 1:S7-S20. **13.** Harvey K, Xu Z, Walker C, et al. *Lipids.* 2014;49(8):777-793. **14.** Xu Z, Harvey KA, Pavlina T, et al. *Nutrients.* 2012;4(8):904-921. **15.** Piper SN, Schade I, Beschmann RB, et al. *Eur J Anaesthesiol.* 2009;26(12):1076-1082. **16.** Antébi H, et al. *JPEN J Parenter Enteral Nutr.* 2004;28(3):142-148.