ASPEN Lipid Injectable Emulsion Safety Recommendations for Adult Patients[1]

- Lipid injectable emulsions (ILEs) are intended as a daily source of energy and fatty acids (FAs) for parenteral nutrition (PN) therapy.
- There are currently four FDA approved ILE products with an adult indication available in the US. Alternative ILE products for adults are those with decreased amounts of soybean oil.

Dosing and Prescribing

- The dose of ILE should be prescribed as amount **per day** (ie, g/d or kcal/d for adults). **Table 1** provides adult daily dosing recommendations.

TABLE 1. ADULT ILE DAILY DOSING RECOMMENDATIONS[2-7]

ILE	SO-ILE	SO,MCT,OO,FO-ILE	OO,SO-ILE
Oil Source	100% soybean oil	30% soybean oil, 30% MCT oil, 25% olive oil, 15% fish oil	80% olive oil, 20% soybean oil
Recommended Dose	Critically ill: <1g/kg/d Stable: 1 g/kg/d	1–2 g/kg/d	1–1.5 g/kg/d
Maximum Dose	2.5 g/kg/d	2.5 g/kg/d	2.5 g/kg/d
Maximum Infusion Rate	0.11 g/kg/h	0.11 g/kg/h	0.11 g/kg/h

Abbreviations: ILE, lipid injectable emulsion; OO,SO-ILE, olive oil, soybean oil ILE—Clinolipid® (Baxter Healthcare Corporation); SO,MCT,OO,FO-ILE, soybean oil, medium-chain triglycerides, olive oil, fish oil ILE—SMOFLipid® (Fresenius Kabi); SO-ILE, soybean oil ILE—Intralipid® (Baxter Healthcare Corporation), Nutrilipid® (B. Braun Medical, Inc).

- The standardized PN order should include the **brand name** of the ILE product due to the variable composition of ILE products.
- With reduced soybean oil products, ILE may be provided to critically ill adults upon PN initiation without producing the inflammatory and immunosuppressive effects associated with SO-ILE.
- Review ILE Prescribing Information for contraindications and prescribe appropriately to avoid allergic reactions. Allergy contraindications for ILEs will vary based on oil source(s) and other active ingredients and excipients.
- Adult minimum EFA recommendations are at least 2%–4% of energy from LA and 0.25%–0.5% of energy from ALA. (See **Table 2**).
  - » Dosing for maintenance or long-term therapy should be about 1 g/kg/day in the stable adult patient.
  - » ILEs that are less than 100% soybean oil require a higher minimum dose vs SO-ILE due to lower LA and ALA content.

TABLE 2. CALCULATED MINIMUM ILE DAILY DOSE TO MEET 2% OF TOTAL KCAL FROM LA[2-5]

Daily total caloric dose	Daily dose SO-ILE (20%)		Daily dose SO,MCT, OO,FO-ILE (20%)		Daily dose OO, SO-ILE (20%)	
kcal	mL*	g	mL*	g	mL*	g
1000	20.4	4.1	62.9	12.6	61.5	12.3
1500	30.6	6.1	94.3	18.9	92.2	18.4
2000	40.8	8.2	125.7	25.1	122.9	24.6
Daily dose, % total kcal to meet ≥ 2% of total kcal from LA	≥ 4.1%		≥ 12.5%		≥ 12.5%	

Abbreviations: ALA, α-linolenic acid; EFA, essential fatty acid; ILE, lipid injectable emulsion; LA, linoleic acid; OO,SO-ILE, olive oil, soybean oil ILE—Clinolipid® (Baxter Healthcare Corporation); SO,MCT,OO,FO-ILE, soybean oil, medium-chain triglycerides, olive oil, fish oil ILE—SMOFLipid® (Fresenius Kabi); SO-ILE, soybean oil ILE—Intralipid® (Baxter Healthcare Corporation), Nutrilipid® (B. Braun Medical, Inc).

ILE LA and ALA Content: [2-5] SO-ILE contains 88-124 mg/mL LA and 8-22 mg/mL ALA; SO,MCT,OO,FO-ILE contains 35 mg/mL LA (mean) and 4.5 mg/mL ALA (mean); OO,SO-ILE contains 35.8 mg/mL LA (mean) and 4.7 mg/mL ALA (mean).

* When dispensing ILE, round up to the nearest mL.

Calculations are based on the mean**ILE content for LA as an amount required to provide at least 2% of total kcal from LA as reported for the products. In certain circumstances, meeting the minimum of 2-4% from LA may not provide the minimum ALA (0.25-0.5%) required. Clinicians should perform additional calculations, refer to product specific information and/or directly communicate with manufacturers to confirm the minimum daily dose needed to also meet minimum ALA requirements. When providing minimum amounts, monitor patient essential fatty acid profiles.

**The mean value of LA for SO-ILE has not been published. A more conservative approach would be to utilize the lowest published value of LA contained in the product.

- The minimum dose to prevent EFAD is **NOT** the daily recommended dose.
- EFA content may vary within a preestablished range which may account for variations of reported amounts in the literature.
- These are minimum estimated dosing recommendations; individuals may require higher ILE dosing to prevent or treat EFAD depending on clinical circumstances.
- Greater than ILE minimum dosing allows for a reduction in the amount of dextrose needed to provide appropriate energy intake.

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Monitoring

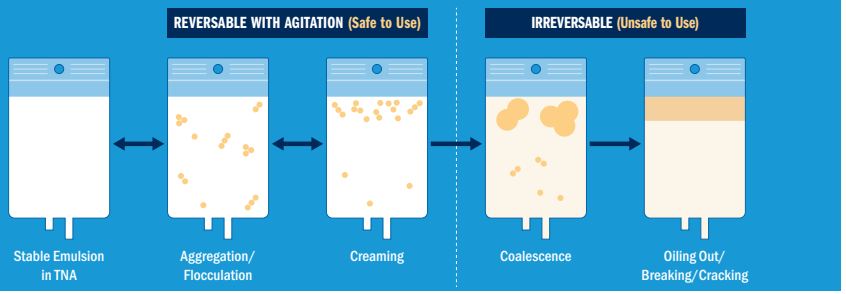
- Check serum triglycerides at baseline and weekly for hospitalized patients and monthly for long-term PN patients.
- Hold or limit ILE if triglyceride level is > 400 mg/dL. Note, withholding ILE greater than 2 weeks is not advised due to risk for EFAD.

Stability/Compatibility

Total Nutrient Admixture (TNA) Stability

- The stability and compatibility of TNA is dependent on many factors including, electrolyte content and specific salts used, final concentration of macronutrients, and pH (These are not the same across all manufacturer's products).
- A pharmaceutical review should be conducted by a knowledgeable pharmacist to assess the stability and compatibility of ILE with the other components of the PN admixture.
- ILE manufacturers should be contacted to determine the acceptable range of macro- and micronutrient concentrations for TNA stability.
- **Figure 1** illustrates phases of TNA physical destabilization:

FIGURE 1. TNA DESTABILIZATION PHASES



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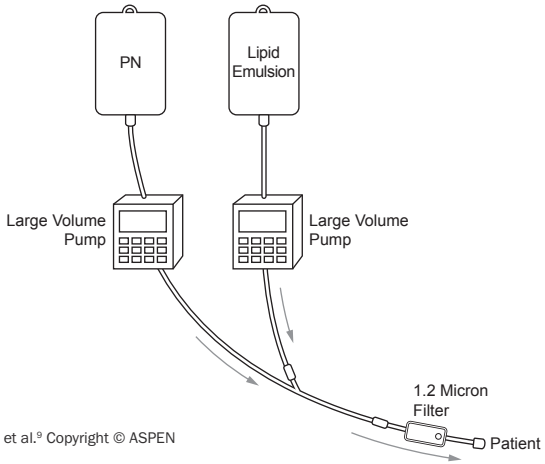
Preparation & Administration

- When ILE is ordered as part of a TNA, it may be infused over 24 hours. If ordered as a separate infusion, it should be infused over a maximum of 12 hours. Can split into two 12 hour doses if needed for volume limitations.
- ILE should be administered using DEHP-free tubing due to concern of DEHP plasticizer leaching into ILE.
- A 1.2 micron filter should be used for a TNA formulation or as a separate ILE infusion. See **Figure 2** for appropriate set-up.[9]
- Administration of medications through the PN venous catheter should be avoided due to increased risk for catheter related blood stream infection (CRBSI) and compatibility concerns.
  - » ILE manufacturers should be contacted for medication compatibility information.

FIGURE 2. APPROPRIATE SET-UP OF PN WITH FILTER



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References

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