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Fresenius Kabi USA Nutrition

Admixture Stability Reference Guide

Adults and pediatrics

The data presented within was obtained from the Medical Affairs Department at Fresenius Kabi USA. How to use this guide:

- Admixture tables are ordered from the lowest concentration of SMOFlipid to the highest concentration and show the final concentrations of the tested admixtures.
- The formulations were tested with the maximum electrolyte content in the additives table and were found to be physically stable. A variety of formulations were tested. Only those formulations that were stable are included in this reference guide.
- Each formulation represents the minimum concentration required of each individual macronutrient to ensure stability. For example, for an admixture to be stable with a final concentration of SMOFlipid 0.9%, the final concentration of Travasol must be at least 5.3% and the final concentration of dextrose must be at least 18.9%.
- SMOFlipid-containing parenteral nutrition (PN) admixtures with Travasol 10%, Clinisol 15%, Plenamine™ 15%, ProSol™ 20%, or TrophAmine® 10% have an 11-day stability (9 days refrigerated at 2°C to 8°C [36°F to 46°F] followed by 48 hours at room temperature from 20°C to 25°C [68°F to 77°F]). SMOFlipid-containing PN admixtures with Premasol 10% have a 10-day stability (9 days refrigerated at 2°C to 8°C [36°F to 46°F] followed by 24 hours at room temperature from 20°C to 25°C [68°F to 77°F]).
- Admixture stability with SMOFlipid was tested by visual inspection, pH, lipid globule size distribution, and mean lipid droplet diameter in compliance with USP <729> standards. No microbiological or chemical tests were conducted. Results are only valid for the branded products listed at the time of testing.
- Additions to the PN admixtures should be evaluated by a pharmacist for compatibility. If it is deemed advisable to introduce additives, use strict aseptic techniques to avoid microbial contamination.
- For detailed information on the data presented in this guide, please contact Fresenius Kabi Medical Affairs at 1-800-551-7176, Option 4.

- **This guide is intended for US audiences only.**
- **Please see the Important Safety Information for Smoflipid at the end of this guide.**

SMOFlipid®
Lipid Injectable Emulsion, USP 20%

SMOFlipid®
Lipid Injectable Emulsion, USP 20%

Adult amino acids

Admixtures tested with SMOFlipid and Travasol 10%, macronutrient final concentrations (%)

11-day admixture stability (9 days refrigerated followed by 48 hours at room temperature)

SMOFlipid 20%[a]	0.9%	1.1%	1.2%	1.3%	1.4%	1.4%	1.5%	2%	2.2%	2.2%	2.6%	3.4%	4.1%	5.7%
Travasol 10%[b]	5.3%	6%	6.8%	7.4%	3.4%	7.9%	4.7%	7.3%	2.1%	5.1%	5.7%	5.8%	2.9%	4%
Dextrose 70%[c]	18.9%	14.1%	7.9%	8.7%	29.7%	9.3%	30%	9.8%	8%	14.7%	10.3%	6.9%	24.7%	11.3%

[a]SMOFlipid 20% tested at 14 - 50 g (0.9% - 5.7% final ILE concentration in admixtures above).
[b]Travasol 10% tested at 21 - 86 g (2.1% - 7.9% final amino acid concentration in admixtures above).
[c]Dextrose 70% tested at 80 - 305 g (6.9% - 30% final dextrose concentration in admixtures above).

Electrolytes and additives in SMOFlipid-containing PN admixtures with Travasol 10%

Electrolytes and Additives	Range
Sodium[a]	0 - 167 mEq/L
Potassium acetate	0 - 150 mEq/L
Calcium gluconate[b]	0 - 10 mEq/L
Magnesium sulfate	0 - 16 mEq/L
(Inorganic) Phosphate	0 - 15 mmol/L
INFUVITE® ADULT (Vial 1 and Vial 2) (Baxter)	10 mL
Tralement®[c] (Trace Elements) (American Regent)	1 mL

[a]The total sodium content includes sodium chloride and sodium phosphates.
[b]Maximum divalent cations (calcium and magnesium) tested 26 mEq/L.
[c]Tralement: Each 1 mL contains: zinc (3 mg), copper (0.3 mg), manganese (55 mcg), and selenium (60 mcg).
Any significant change in pH from additives not listed compared to what has been evaluated in this study may affect compatibility.

Admixtures tested with SMOFlipid and Clinisol 15%, macronutrient final concentrations (%)

11-day admixture stability (9 days refrigerated followed by 48 hours at room temperature)

SMOFlipid 20%[a]	0.6%	0.7%	0.8%	1.2%	1.3%	1.4%	1.4%	1.5%	1.6%	1.7%	2.1%	2.4%
Clinisol 15%[b]	9.5%	8.8%	3.2%	6.7%	6.4%	2%	7.7%	8.5%	9.1%	4%	4.9%	7.9%
Dextrose 70%[c]	13.5%	15.7%	7%	23.8%	25.5%	5%	18.2%	10%	10.7%	34.2%	28.1%	10%

SMOFlipid 20%[a]	2.7%	3%	3.3%	3.4%	3.8%	4.4%	4.5%	4.6%	5.3%	5.5%	5.5%	6.7%
Clinisol 15%[b]	6.4%	2.6%	7.3%	5.8%	6.5%	7.5%	6.7%	3.3%	5%	6.5%	3.8%	4.7%
Dextrose 70%[c]	18.3%	8.5%	13.2%	20.5%	15.4%	8.8%	12.7%	27.8%	17.6%	9.3%	21.9%	13.4%

[a]SMOFlipid 20% tested at 6.4 - 90 g (0.6% - 6.7% final ILE concentration in admixtures above).
[b]Clinisol 15% tested at 20 - 150 g (2% - 9.5% final amino acid concentration in admixtures above).
[c]Dextrose 70% tested at 50 - 300 g (5% - 34.2% final dextrose concentration in admixtures above).

Electrolytes and additives in SMOFlipid-containing PN admixtures with Clinisol 15%

Electrolytes[a] and Additives	Range
Sodium	0 - 151 mEq/L
Potassium	0 - 150 mEq/L
Calcium	0 - 10 mEq/L
Magnesium	0 - 16 mEq/L
(Inorganic) Phosphate[b]	0 - 15 mmol/L
INFUVITE® ADULT (Vial 1 and Vial 2) (Baxter)	10 mL
Tralement®[c] (Trace Elements) (American Regent)	1 mL

[a]The electrolyte salts were sodium chloride, potassium acetate, calcium gluconate, magnesium sulfate, and sodium phosphates.
Maximum divalent cations (calcium and magnesium) tested 26 mEq/L.
[b]The same limits are valid when additions of organic phosphate, sodium glycerophospate (Glycophos®) are used.
[c]Tralement: Each 1 mL contains: zinc (3 mg), copper (0.3 mg), manganese (55 mcg), and selenium (60 mcg).
Any significant change in pH from additives not listed compared to what has been evaluated in this study may affect compatibility.

Infuse admixtures containing SMOFlipid immediately. Infusion must be complete within 24 hours after removal from refrigeration. Discard any remaining admixture.

SMOFlipid®
Lipid Injectable Emulsion, USP 20%

Adult amino acids

Admixtures tested with SMOFlipid and Plenamine 15%, macronutrient final concentrations (%)

11-day admixture stability (9 days refrigerated followed by 48 hours at room temperature)

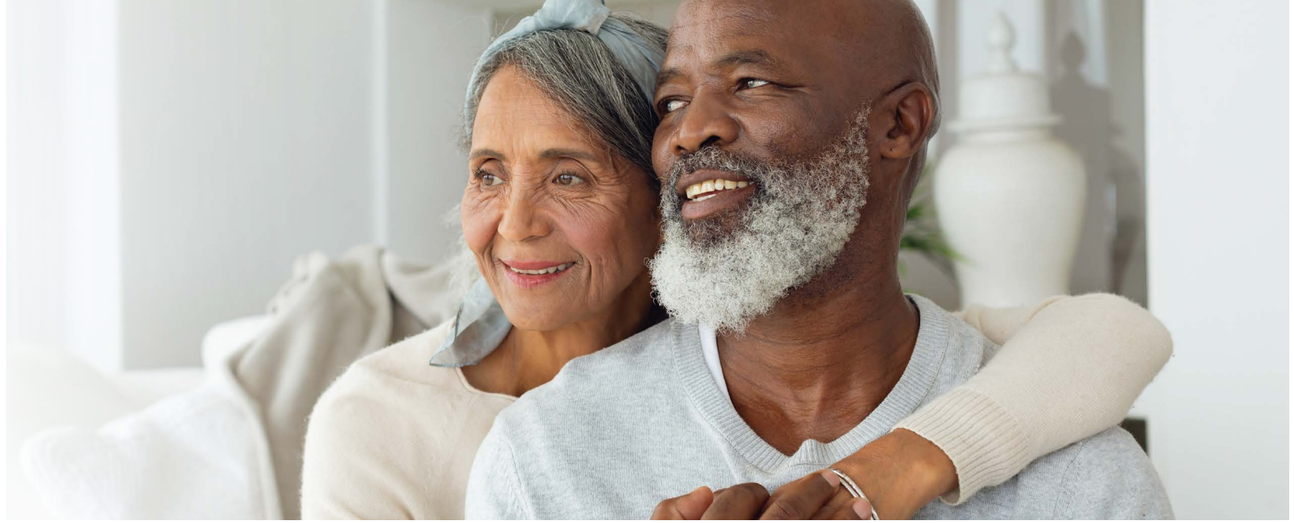
SMOFlipid 20%[a]	1.2%	1.4%	1.6%	1.6%	1.7%	2.1%	2.7%	3.3%	3.4%	3.8%	4.4%	4.6%	5.5%	6.7%
Plenamine 15%[b]	6.7%	7.7%	9.1%	9.2%	4%	4.9%	6.4%	7.3%	5.8%	6.5%	7.5%	3.3%	3.8%	4.7%
Dextrose 70%[c]	23.8%	18.2%	10.7%	10.8%	34.2%	28.1%	18.3%	13.2%	20.5%	15.4%	8.8%	27.8%	21.9%	13.4%

[a]SMOFlipid 20% tested at 15 - 50 g (1.2% - 6.7% final ILE concentration in admixtures above).
[b]Plenamine 15% tested at 35 - 85 g (3.3% - 9.2% final amino acid concentration in admixtures above).
[c]Dextrose 70% tested at 100 - 300 g (8.8% - 34.2% final dextrose concentration in admixtures above).

Electrolytes and additives in SMOFlipid-containing PN admixtures with Plenamine 15%

Electrolytes and Additives	Maximum Amount Tested
Sodium[a]	151 mEq/L
Potassium acetate	151 mEq/L
Calcium gluconate[b]	10 mEq/L
Magnesium sulfate	16 mEq/L
(Inorganic) Phosphate	15 mmol/L
INFUVITE® ADULT (Vial 1 and Vial 2) (Baxter)	10 mL
Tralement®[c] (Trace Elements) (American Regent)	1 mL

[a]The total sodium content includes sodium chloride and sodium phosphates.
[b]Maximum divalent cations (calcium and magnesium) tested 26 mEq/L.
[c]Tralement: Each 1 mL contains: zinc (3 mg), copper (0.3 mg), manganese (55 mcg), and selenium (60 mcg).
Any significant change in pH from additives not listed compared to what has been evaluated in this study may affect compatibility.



Admixtures tested with SMOFlipid and ProSol 20%, macronutrient final concentrations (%)

11-day admixture stability (9 days refrigerated followed by 48 hours at room temperature)

SMOFlipid 20%[a]	1.2%	1.4%	1.6%	1.6%	1.7%	2.1%	2.7%	3.3%	3.4%	3.8%	4.4%	4.6%	5.5%	6.7%
ProSol 20%[b]	6.7%	7.7%	9.1%	9.2%	4%	4.9%	6.4%	7.3%	5.8%	6.5%	7.5%	3.3%	3.8%	4.7%
Dextrose 70%[c]	23.8%	18.2%	10.7%	10.8%	34.2%	28.1%	18.3%	13.2%	20.5%	15.4%	8.8%	27.8%	21.9%	13.4%

[a]SMOFlipid 20% tested at 15 - 50 g (1.2% - 6.7% final ILE concentration in admixtures above).
[b]ProSol 20% tested at 35 - 85 g (3.3% - 9.2% final amino acid concentration in admixtures above).
[c]Dextrose 70% tested at 100 - 300 g (8.8% - 34.2% final dextrose concentration in admixtures above).

Electrolytes and additives in SMOFlipid-containing PN admixtures with ProSol 20%

Electrolytes and Additives	Maximum Amount Tested
Sodium[a]	151 mEq/L
Potassium acetate	150 mEq/L
Calcium gluconate[b]	10 mEq/L
Magnesium sulfate	16 mEq/L
(Inorganic) Phosphate	15 mmol/L
INFUVITE® ADULT (Vial 1 and Vial 2) (Baxter)	10 mL
Tralement®[c] (Trace Elements) (American Regent)	1 mL

[a]The total sodium content includes sodium chloride and sodium phosphates.
[b]Maximum divalent cations (calcium and magnesium) tested 26 mEq/L.
[c]Tralement: Each 1 mL contains: zinc (3 mg), copper (0.3 mg), manganese (55 mcg), and selenium (60 mcg).
Any significant change in pH from additives not listed compared to what has been evaluated in this study may affect compatibility.

Infuse admixtures containing SMOFlipid immediately. Infusion must be complete within 24 hours after removal from refrigeration. Discard any remaining admixture.

SMOFlipid®
Lipid Injectable Emulsion, USP 20%

Pediatric amino acids

Admixtures tested with **SMOFlipid** and **TrophAmine** 10%, macronutrient final concentrations (%)

11-day admixture stability (9 days refrigerated followed by 48 hours at room temperature)

Admixtures[a]			
SMOFlipid 20%	2.1%	3.2%	3.6%
TrophAmine 10%	2.9%	4.3%	4.8%
Dextrose 70%	17.2%	21.6%	10.3%
Volume (mL)	280	280	250
Micronutrients			
Sodium chloride (mEq/kg/day)	5	2	2
Potassium acetate (mEq/kg/day)	4	2	2
Calcium gluconate (mEq/kg/day)	8	2	2
Magnesium sulfate (mEq/kg/day)	0.5	0.3	0.3
Sodium phosphate (mmol/kg/day)	2	1	1
INFUVITE® PEDiatric (mL/day) (Baxter)	3.25	3.25	3.25
Selenium (selenious acid) (mcg/kg/day) (American Regent)	2	2	2
Zinc sulfate (mcg/kg/day) (American Regent)	400	250	250
Copper (cupric chloride) (mcg/kg/day) (Hospira)	20	20	20
Chromium (chromic chloride) (mcg/kg/day) (Hospira)	0.3	0.2	0.2
Manganese sulfate (mcg/kg/day) (American Regent)	1	1	1
Cysteine hydrochloride[b] (mg/kg/day) (Exela Pharma Sciences)	160	0	0

[a]SMOFlipid admixture 2.1% concentration was based on a 2-kg infant; SMOFlipid admixtures 3.2% and 3.6% concentrations were based on a 3-kg infant.
[b]Cysteine was only added to SMOFlipid admixture 2.1% concentration; only evaluated in admixture based on a 2-kg infant.
Any significant change in pH from additives not listed compared to what has been evaluated in this study may affect compatibility.

Admixtures tested with **SMOFlipid** and **Premasol** 10%, macronutrient final concentrations (%)

10-day admixture stability (9 days refrigerated followed by 24 hours at room temperature)

Admixtures[a]			
SMOFlipid 20%	2.3%	3%	3.2%
Premasol 10%	3%	3%	4.3%
Dextrose 70%	10.9%	25%	21.6%
Volume (mL)	200	360	280
Micronutrients			
Sodium chloride 23.4% (mEq/kg/day)	2	5	2
Potassium acetate (mEq/kg/day)	2	4	2
Calcium gluconate 10% (mEq/kg/day)	2	4	2
Magnesium sulfate 50% (mEq/kg/day)	0.3	0.5	0.3
Sodium phosphate (mmol/kg/day)	1	2	1
INFUVITE® PEDiatric (mL/day) (Vial 1 and Vial 2) (Baxter)	3.25	5	3.25
Multitrace-4® Neonatal[b] (Trace Elements) (mL/day) (American Regent)	0.3	0.4	0.6

[a]SMOFlipid admixture 2.3% concentration was based on a 1.5-kg infant; SMOFlipid admixture 3% concentration was based on a 3.6-kg infant; SMOFlipid admixture 3.2% concentration was based on a 3-kg infant.
[b]Neonatal Multitrace: each 1 mL contains: zinc (1.5 mg), copper (0.1 mg), manganese (25 mcg), and chromium (0.85 mcg).
Any significant change in pH from additives not listed compared to what has been evaluated in this study may affect compatibility.

Infuse admixtures containing SMOFlipid immediately. Infusion must be complete within 24 hours after removal from refrigeration. Discard any remaining admixture.

SMOFlipid®
Lipid Injectable Emulsion, USP 20%

Please scan this QR code to see the full Prescribing Information

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 (≥5%) from clinical trials in adults were nausea, vomiting, and hyperglycemia. Most common adverse drug reactions (≥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.

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

Notes:

Notes:

If you have any questions, please contact medical information at 1.800.551.7176 (option 4) or email

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