



14 September 2007

**ISDI COMMENTS ON
Draft Revised Advisory List of Nutrient Compounds for Use in Foods for
Special Dietary Uses Intended for the Use by Infants and Young Children**

At Step 6 of the procedure

Answer to CL 2007/23-NFSDU

B: ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children					ISDI Comments	
	CAC ²	international and/or national bodies	IF		FUF	PCBF	CBF		FSMP for inf. & YC
			Sec. A	Sec. B					
4. Vitamin E									
4.7 DL-alpha-Tocopheryl polyethylene glycol 1000 succinate		FCC, USP		√				√	This nutrient does have a USP monograph.

C: ADVISORY LIST OF AMINO ACIDS AND OTHER NUTRIENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children					ISDI Comments	
	CAC ²	international and/or national bodies	IF		FUF	PCBF	CBF		FSMP for inf. & YC
			Sec. A	Sec. B					
6. Nucleotides									
{6.5 Disodium Uridine 5-monophosphate salt}		FSANZ, Jap Food Std	{√}	{√}	{√}	-	-	{√}	ISDI would like that the square brackets around

{6.6 Disodium Guanosine 5-monophosphate salt}		FCC, JECFA, FSANZ, Jap Food Std	{√}	{√}	{√}	-	-	{√}	those nutrients are deleted since those nucleotides are commonly used in those products by the manufacturers.
{6.7 Disodium Inosine 5-monophosphate salt}		FCC, JECFA, FSANZ, Jap Food Std	{√}	{√}	{√}	-	-	{√}	
8. Others									
8.1 Lutein		JECFA (2004)	√	√	√			√	ISDI would like to see those nutrients added to the list as used in those products.
8.2 Zeaxanthin		JECFA (2004)	√	√	√			√	
8.3 Lycopene		JECFA (2006)	√	√	√			√	
8.3 Mixed Carotenes		JECFA (FNP 52 Add 6 (1998))	√	√	√			√	

8.1 – Lutein

Lutein satisfies the criteria for inclusion of nutrient compounds from the advisory lists, as set forth in Section 2 of the CCNFSDU Advisory Lists, as follows:

(a) They are shown to be safe and appropriate for the intended use as nutrient sources for infants and young children:

- Lutein is in human milk,¹ is not synthesized by the body and is concentrated in the retina.² In vitro and animal studies suggest that lutein is a biological antioxidant and filter of blue light.^{3,4}
- Safety of the ingredient is provided in the toxicological monograph.⁵
- The US Food and Drug Administration (FDA) accepted the independent determination of an expert panel that FloraGLO® lutein is generally recognized as safe (GRAS) for use in several food categories, including infant and toddler foods. The notification to FDA did not include the use of lutein in infant formula at that time.⁶ Subsequently, in April 2007 FDA received a follow up notification that the same expert panel had reviewed the safety of the addition of lutein to infant formulas and Kemin Health LLC has requested the FDA to extend the scope of the use of

¹ Canfield,L.M.; Clandinin,M.T.; Davies,D.P.; Fernandez,M.C.; Jackson,J.; Hawkes,J.; Goldman,W.J.; Pramuk,K.; Reyes,H.; Sablan,B.; Sonobe,T.; Bo,X. (2003) Multinational study of major breast milk carotenoids of healthy mothers. Eur. J. Nutr.42: 133-141.

² Bernstein PS, Khachik F, Carvalho LS, Muir GJ, Zhao D-Y, Katz NB. Identification and quantitation of carotenoids and their metabolites in the tissues of the human eye. Exp Eye Res. 2001;72:215-223.

³ Khachik F, Bernstein PS, Garland DL Identification of lutein and zeaxanthin oxidation products in human and monkey retinas. Invest Ophthalmol Vis Sci. 1997;38:1802-1811.

⁴ Barker F, Neuringer M, Johnson E, Schalch W, Koepcke W, Snodderly DM Dietary zeaxanthin or lutein improves foveal photo-protection from blue light in xanthophyll-free monkeys Investigative Ophthalmology & Visual Science 2005; 46:E-Abstract 1770.

⁵ Safety Evaluation of Certain Food Additives: Prepared by the Sixty-third Meeting of the Joint FAO/WHO Expert Committee on Food Additives. Food and Agriculture Organization of the United Nations (FAO) / World Health Organization (WHO). WHO Food Additives Series. June 8-17, 2004. No. 54, pp 49-86 & 637-638 (http://whqlibdoc.who.int/publications/2006/9241660546_eng.pdf).

⁶ FDA/CFSAN (Food and Drug Administration, Center for Food Safety and Applied Nutrition) Agency Response Letter: GRAS Notice No GRN 000140; 2004.

lutein to include infant formula.⁷ A letter of no objection is expected no later than October 1, 2007.

- Clinical trials confirm the safety of the addition of lutein to infant and follow-on formulas^{8,9}
 - Infant and follow-on formulas containing lutein are currently on the market in several Codex countries, including Mexico and Hong Kong.
 - Applications for the addition of lutein to infant and follow-on formulas are under review in several countries, including the European Union,¹⁰ Australia and New Zealand (FSANZ).¹¹
- (b) It is demonstrated by appropriate studies in animals and/or humans that the nutrients are biologically available:
- Results from a clinical trial and a summary of relevant animal data confirm the bioavailability of lutein from infant formula.¹²
- (c) The purity requirements of the nutrient compounds conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in the absence of such specifications, with another internationally recognized specification. If there is no internationally recognized specification, national purity requirements that have been evaluated according to or similar to a FAO/WHO process may be considered:
- Lutein is listed in the JECFA Compendium Addendum 12/FNP 52 Add. 12/35.
- (d) The stability of nutrient compound(s) in the food(s) in which it is (they are) to be used can be demonstrated:
- Stability of lutein in infant and follow-on formulas has been studied. In preliminary stability studies in representative ready-to-feed (RTF) infant formulas, fortification levels were selected from data on lutein concentrations in human milk, manufacturing experience with nutrient stability, information from the literature, and advice from the supplier. Formulas were manufactured and the levels of lutein were determined at selected intervals over the course of shelf life. The results from these stability studies were reviewed and fortification levels for sustainable commercial manufacture were selected.

8.2 – Zeaxanthin

Zeaxanthin satisfies the criteria for inclusion of nutrient compounds from the advisory lists, as set forth in Section 2 of the CCNFSDU Advisory Lists, as follows:

- (a) They are shown to be safe and appropriate for the intended use as nutrient sources for infants and young children:
- Safety of the ingredient is provided in the toxicological monograph.¹³

⁷ GRN# 221 From Kemin Health LCC, for Lutein as an ingredient in term infant formula at a maximum level of 250 micrograms/liter, dated April 11, 2007. Available at <http://www.cfsan.fda.gov/~rdb/opa-gn07.html>

⁸ MJ Kullen, J Bettler, K Ramanujam, J Lebumfacil, N Calimon, M Capeding, S Troemel, J O'Connell and B Harris. The bioavailability of lutein from infant formula. *The FASEB Journal*. 2007;21:A728.

⁹ R Capeding, N Calimon, J Lebumfacil, AM Davis, RM Kline, BJ Harris. Addition of a new ingredient lutein to infant formula fed to healthy term infants in a growth and safety trial. Presented at 30th Congress of the Union of Mediterranean-Middle Eastern Pediatrics Societies, Sept. 4-7, 2006, Damascus, Syria.

¹⁰ EFSA-Q-2007-095 Lutein for the particular use by infants and young children, Available at http://www3.efsa.europa.eu/register/qr_panels_29_en.html.

¹¹ FSANZ Application 594, Lutein as a nutritive substance in infant formula (includes follow on formula).

¹² Bernstein PS, Khachik F, Carvalho LS, Muir GJ, Zhao D-Y, Katz NB. Identification and quantitation of carotenoids and their metabolites in the tissues of the human eye. *Exp Eye Res*. 2001;72:215-223.

- (b) It is demonstrated by appropriate studies in animals and/or humans that the nutrients are biologically available:
- The bioavailability of carotenoids from food is variable depending on whether they are part of the plant matrix or have been purified and formulated. Most of the studies are with adult subjects. With raw plants such as leafy green vegetables or carrots, absorption can be less than 5%, while with an oil emulsion or water-dispersible microbeadlets more than 50%. Co-consumption with dietary fat also optimizes carotenoid absorption.¹⁴ An adult, two-week, controlled feeding trial with carotenoid-rich foods demonstrated how a 2.5X increase in carotenoid content resulted in approximately a 20% increase (lutein, zeaxanthin, lycopene) or 40% increase (β -carotene, α -carotene) in plasma concentrations.¹⁵ Healthy adults taking either 1 mg/day or 10 mg/day of synthetic zeaxanthin beadlets for 42 days had, respectively, a 4-fold or 20-fold increase in plasma zeaxanthin.¹⁶
 - There is evidence that carotenoids are absorbed from breast milk. In a mother:infant population (n=173) from Malawi, the mothers' serum zeaxanthin correlated with the infants' serum zeaxanthin (corr coeff 0.280; P<0.0002).¹⁷
- (c) The purity requirements of the nutrient compounds conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in the absence of such specifications, with another internationally recognized specification. If there is no internationally recognized specification, national purity requirements that have been evaluated according to or similar to a FAO/WHO process may be considered:
- Zeaxanthin is listed in the JECFA Compendium Addendum 12/FNP 52 Add. 12/61.
- (d) The stability of nutrient compound(s) in the food(s) in which it is (they are) to be used can be demonstrated:
- Manufacturing experience with adult medical enteral nutrition products confirms that β -carotene and lutein is stable for the normal shelf life expected of the products. The same is true for infant formula with β -carotene. Although not yet evaluated, stability of the other carotenoids is expected to be similar in nature. Consultation with several ingredient supplier companies suggests that formulation overage of 20% will compensate for heat-processing and shelf life losses. An actual overage content would need to be determined based on actual stability testing of each product.

¹³ Safety Evaluation of Certain Food Additives: Prepared by the Sixty-third Meeting of the Joint FAO/WHO Expert Committee on Food Additives. Food and Agriculture Organization of the United Nations (FAO) / World Health Organization (WHO). WHO Food Additives Series. June 8-17, 2004. No. 54, pp 159-187 & 637-638 (http://whqlibdoc.who.int/publications/2006/9241660546_eng.pdf).

¹⁴ β -Carotene and other carotenoids. IN: *Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids*. Institute of Medicine. National Academy Press. 2000. pp. 325-382.

¹⁵ Brevik A, et al. Six carotenoids in plasma used to assess recommended intake of fruits and vegetables in a controlled feeding study. *Eur J Clin Nutr* 2004;58:1166-73.

¹⁶ Hartmann D, et al. Plasma kinetics of zeaxanthin and 3'-dehydro-lutein after multiple oral doses of synthetic zeaxanthin. *Am J Clin Nutr* 2004;79:410-417.

¹⁷ Dancheck B, et al. Status of carotenoids, vitamin A, and vitamin E in the mother-infant dyad and anthropometric status of infants in Malawi. *J Health Popul Nutr* 2005;23:343-50.

8.3 – Lycopene

Lycopene satisfies the criteria for inclusion of nutrient compounds from the advisory lists, as set forth in Section 2 of the CCNFSDU Advisory Lists, as follows:

- (a) They are shown to be safe and appropriate for the intended use as nutrient sources for infants and young children:
- Lycopene is naturally found in human milk.¹⁸
 - Safety of lycopene is provided in a toxicological monograph¹⁹ and primary literature.
 - Clinical safety data have been collected to support the addition of lycopene to infant formula.^{20,21,22}
- (b) It is demonstrated by appropriate studies in animals and/or humans that the nutrients are biologically available:
- A clinical study of infants was conducted to assess the relative bioavailability of lycopene in a milk-based infant formula. Three formulas were studied in the trial: 1) no added lycopene (CTRL); 2) level 1 lycopene, targeted to 100% bioavailability compared to human milk (L1); and 3) level 2 lycopene, targeted to 50% bioavailability (L2). Infants were studied for 56 d. At the end of the study, the daily intake of lycopene in infants fed the CTRL formula was 0 ± 0 mcg/kg body weight. Intake of lycopene in infants fed the L1 formula was 5.74 ± 0.41 mcg/kg body weight and in infants fed the L2 formula was 11.68 ± 0.90 mcg/kg body weight. Plasma lycopene concentrations significantly increased with increasing concentrations of lycopene in the formulas. Results from the clinical study indicated that the lycopene-supplemented formulas were well tolerated and safe. The lycopene in the formulas was bioavailable and provided formula fed infants with a nutrient that is naturally found in human milk.
- (c) The purity requirements of the nutrient compounds conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in the absence of such specifications, with another internationally recognized specification. If there is no internationally recognized specification, national purity requirements that have been evaluated according to or similar to a FAO/WHO process may be considered:
- Lycopene (synthetic) and lycopene from *Blakeslea Trispora* are listed in the JECFA Compendium of Food Additive Specifications from 2006.²³
- (d) The stability of nutrient compound(s) in the food(s) in which it is (they are) to be used can be demonstrated:

¹⁸ Canfield,L.M.; Clandinin,M.T.; Davies,D.P.; Fernandez,M.C.; Jackson,J.; Hawkes,J.; Goldman,W.J.; Pramuk,K.; Reyes,H.; Sablan,B.; Sonobe,T.; Bo,X. (2003) Multinational study of major breast milk carotenoids of healthy mothers. *Eur. J. Nutr.*42: 133-141.

¹⁹ Safety Evaluation of Certain Food Additives: Prepared by the Sixty-Seventh Report of the Joint FAO/WHO Expert Committee on Food Additives. Food and Agriculture Organization of the United Nations (FAO) / World Health Organization (WHO). WHO Technical Report Series. 2007, No. 940, pp 15-21.

²⁰ McClain, R.M. and Bausch, J. (2003) Summary of safety studies conducted with synthetic lycopene. *Reg. Toxicol. Pharmacol.* 37: 274-285.

²¹ Christian, M.S., Schulte, S., Hellwig, J. (2003) Developmental (embryo-fetal toxicity/teratogenicity) toxicity studies of synthetic crystalline lycopene in rats and rabbits. *Food Chem. Toxicol.* 41: 773-783.

²² Mellert, W. Deckhardt, K., Gembardt, C., Schulte, S., Van Ravenzwaay, B., Slesinski, R.S. (2002) Thirteen-week oral toxicity study of synthetic lycopene products in rats. *Food Chem. Toxicol.* 40: 1581-1588.

²³ Compendium of Food Additive Specifications. Joint FAO/WHO Expert Committee on Food Additives. 67th Meeting 2006. Food and Agriculture Organization of the United Nations. Rome, 2006. Pages 35-44. (<ftp://ftp.fao.org/docrep/fao/009/a0675e/a0675e00.pdf>).

- See Appendix I.

8.4 – Mixed Carotenes

Mixed Carotenes satisfies the criteria for inclusion of nutrient compounds from the advisory lists, as set forth in Section 2 of the CCNFSDU Advisory Lists, as follows:

- (a) They are shown to be safe and appropriate for the intended use as nutrient sources for infants and young children:
 - In children, low blood concentrations of carotenoids correlates with poor anthropometric status, including low body weight.⁹ Malnutrition of the nursing mother lowers breast milk concentrations of carotenoids^{9,24,25,26,27,28,29,30} and compromises the health of the nursing child. Dancheck cites several studies in which the carotenoid status of breastfeeding infants correlated to that of the mothers, and others in which low carotenoid status linked to stunted growth.⁹
- (b) It is demonstrated by appropriate studies in animals and/or humans that the nutrients are biologically available:
 - The bioavailability of carotenoids from food is variable depending on whether they are part of the plant matrix or have been purified and formulated. Most of the studies are with adult subjects. With raw plants such a leafy green vegetables or carrots, absorption can be less than 5%, while with an oil emulsion or water-dispersible microbeadlets more than 50%. Co-consumption with dietary fat also optimizes carotenoid absorption.⁶ An adult, two-week, controlled feeding trial with carotenoid-rich foods demonstrated how a 2.5X increase in carotenoid content resulted in approximately a 20% increase (lutein, zeaxanthin, lycopene) or 40% increase (β -carotene, α -carotene) in plasma concentrations.⁷
 - There is evidence that carotenoids are absorbed from breast milk:
 - β -carotene: After 10 days of feeding nursing mothers red palm oil the breast milk content increased from 35 nmol/L to 88 nmol/L but infants' serum β -carotene did not increase.¹⁶ In a mother:infant population (n=173) from Malawi, the mothers' serum β -carotene correlated with the infants' serum β -carotene (corr coeff 0.269; P<0.001).⁹ Dijkhuizen et al showed in Indonesia that breast milk β -carotene correlated with both mothers' and infants' plasma concentrations.¹⁸
 - α -carotene: After 10 days of feeding nursing mothers red palm oil the breast milk content increased from 10 nmol/L to 33 nmol/L and the infants' serum α -carotene increased by 53% (P<0.001).¹⁶ In a mother:infant population (n=173) from Malawi, the mothers' serum α -carotene correlated with the infants' serum β -carotene (corr coeff 0.254; P<0.001).⁹

²⁴ Canfield LM, et al. Red palm oil in the maternal diet increases provitamin A carotenoids in breast milk and serum of the mother-infant dyad. *Eur J Nutr* 2001;40:30-38.

²⁵ Allen CM, et al. Tomato consumption increases lycopene isomer concentrations in breast milk and plasma of lactating women. *Am Diet Assoc* 2002;102:1257-62.

²⁶ Dijkhuizen MA, et al. Concurrent micronutrient deficiencies in lactating mothers and their infants in Indonesia. *Am J Clin Nutr* 2001;73:786-791.

²⁷ Dijkhuizen MA et al. Zinc plus β -carotene supplementation of pregnant women superior to β -carotene supplementation alone in improving vitamin A status in both mothers and infants. *Am J Clin Nutr* 2004;80:1299-307.

²⁸ Jewell VC, et al. Nutritional factors and visual function in premature infants. *Proc Nutr Soc* 2001;60:171-178.

²⁹ Rice AL, et al. Maternal vitamin A or β -carotene supplementation in lactating Bangladeshi women benefits mothers and infants but does not prevent subclinical deficiency. *J Nutr* 1999;129:356-365.

³⁰ Sommerburg O, et al. Carotenoid supply in breast-fed and formula-fed neonates. *Eur J Pediatr* 2000;159:86-90.

(c) The purity requirements of the nutrient compounds conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in the absence of such specifications, with another internationally recognized specification. If there is no internationally recognized specification, national purity requirements that have been evaluated according to or similar to a FAO/WHO process may be considered:

- Carotenes (vegetable) are listed in the JECFA FNP 52 Add 6 (1998)³¹

(d) The stability of nutrient compound(s) in the food(s) in which it is (they are) to be used can be demonstrated:

- Manufacturing experience with adult medical enteral nutrition products confirms that β -carotene and lutein is stable for the normal shelf life expected of the products. The same is true for infant formula with β -carotene. Although not yet evaluated, stability of the other carotenoids is expected to be similar in nature. Consultation with several ingredient supplier companies suggests that formulation overage of 20% will compensate for heat-processing and shelf life losses. An actual overage content would need to be determined based on actual stability testing of each product.

LIST OF NUTRIENT COMPOUNDS THAT LACK OFFICIAL PURITY REQUIREMENTS

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children						ISDI Comments
	CAC ²	international and/or national bodies	IF		FUF	PCBF	CBF	FSMP for inf. & YC	
			Sec. A	Sec. B					
LIST A									
{Copper-lysine-complex}	?	?	{√}	{√}	{√}	{√}	{√}	{√}	This nutrient is authorised for use in Europe (Dir. 2001/15/EC) as a source of copper
{Zinc citrate}	?	?	[√]	[√]	[√]	[√]	[√]	[√]	This nutrient is authorised for use in Europe (Dir. 2001/15/EC) as a source of zinc

³¹ <http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-115.pdf>.

LIST B									
[Pyridoxal dipalmitate] Pyridoxine dipalmitate	?	?		{√}		{√}	{√}	{√}	ISDI believes that the name of the substance should read 'pyridoxine dipalmitate' instead of 'Pyridoxal dipalmitate'. Pyridoxine dipalmitate is a nutrient authorised for use in Europe (Dir. 2001/15/EC) as a source of Vitamine B ₆ .
LIST C									
ISDI: [calcium-L-methylfolate] ³²	?	JECFA 2005	{√}	{√}				{√}	This nutrient has also been evaluated by EFSA and is now authorised for use in Europe (Dir. 2001/15/EC) as a source of folate
LIST D									
[Uridine 5-monophosphate sodium salt]	?	?	{√}	{√}	{√}			{√}	ISDI believes that those nutrients can be deleted from the list since they are not used by the manufacturers of those products
[Guanosine 5-monophosphate sodium salt]	?	?	{√}	{√}	{√}			{√}	
[Inosine 5-monophosphate sodium salt]	?	?	{√}	{√}	{√}			{√}	
[Cytidin 5-monophosphate sodium salt]	?	?	{√}	{√}	{√}			{√}	
[Uridine 5-monophosphate (UMP)]	?	?	{√}	{√}	{√}			{√}	
[Adenosine 5-monophosphate sodium salt]	?	?	{√}	{√}	{√}			{√}	

³² calcium-L-methylfolate = calcium-5-methyl-tetrahydrofolic acid

D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS

	INS no.	Additive/Carrier	Maximum Level in Ready-to-use Food {mg/kg}
(a)	414	Gum acacia (gum acacia)	{10} or {100}

Justification: ISDI supports the level of 100 mg/kg for Gum acacia as a carrier of nutrients.

This additive is more and more used by the industry instead of additives with an animal origin and due to the procedures followed for the fabrication of premixes, the amount of INS 414 needed for the premixes will result in levels in the final product that can be between 10 and 100 mg/kg.

APPENDIX I: STABILITY OF LYCOPENE IN INFANT AND FOLLOW-ON FORMULAE

Stability of lycopene in infant formula has been studied. Fortification levels were selected from data on lycopene concentrations in human milk, manufacturing experience with nutrient stability, and information from the literature. Formulas were manufactured and the levels of lycopene were determined at selected intervals over the course of shelf life.

The fortification levels of lycopene for infant formulas were based on published data for human milk levels and a reasonable assumption of an approximate 50-90% bioavailability compared to human milk. The target lycopene concentrations examined during stability testing were reflective of 100% (L1) and 50% (L2) bioavailability compared to human milk.

Commercial scale stability studies were conducted using synthetic lycopene in milk-based liquid (RTF) and powder infant formulas. Lycopene levels were determined at defined intervals throughout storage.

RTF infant formulas with target levels of lycopene (L1 and L2) were manufactured in a commercial manufacturing facility at a scale representative of typical commercial production.

During the stability program, samples stored at room temperature were withdrawn at regular intervals over 12 months for RTF and 6 months for powder. Lycopene content of the samples was measured by HPLC. Lycopene content remained stable during storage when fortified to L1 and L2 target levels in RTF (Table 1) and powder (Table 2) formulas.

Table 1: Lycopene Stability in Ready to Feed Infant Formula Supplemented with Two Levels of Lycopene

Target fortification level	Length of Storage (months) % baseline (0 months) ¹			
	0	4	8	12
L1	100	93	98	109
L2	100	92	102	121

Values based on analysis of one sample from each batch.

¹Lycopene stability expressed as percent baseline value = lycopene concentration @ 4, 8, or 12 months/baseline lycopene concentration x 100.

Table 2: Lycopene Stability in Powder Infant Formula Supplemented with Two Levels of Lycopene

Target fortification level	Length of Storage (months) % baseline (0 months) ^{1,2}		
	0	3	6
L1	100	92	92
L2	100	104	95

¹ Lycopene stability expressed as percent baseline value = lycopene concentration @ 3 or 6 months/baseline lycopene concentration x 100.

² Formula reconstituted to 20 kcal/fl. oz.

Values based on analysis of one sample from each batch.