

RT9-2027 TECHNICAL SPECIFICATIONS

SUPPLY AND DELIVERY OF SPECIALISED PRODUCTS FOR INFANT FEED, COMPLETE ENTERAL FEEDS FOR PAEDIATRICS AND ADULTS, ENTERAL FEED SUPPLEMENTS, OTHER NUTRITIONAL SUPPLEMENTS, AND TUBE FEEDING SYSTEMS TO THE STATE FOR 36 MONTHS

LIST OF ABBREVIATIONS

Abbreviation	Full Name
°C	Degrees Celsius
BCAA	Branched-chain amino acids
BPA-free	Bisphenol A-free
Bq/kg	Becquerels per kilogram
CCPs	Critical control points
CFU/g	Colony-forming units per gram
CoA	Certificate of Analysis
EPA	Eicosapentaenoic acid
FAO	Food and Agriculture Organization of the United Nations
G	Gram
GHPs	Good hygienic practices
GMPs	Good manufacturing practices
GORD	Gastro-oesophageal reflux disease
GUL	Guidance Upper Limit
kcal	Kilocalorie
Kj	Kilojoule
LCTs	Long-chain triglycerides
L-form	L-form (the biologically active form of an amino acid)
mcg	Microgram
mcg RE	Microgram retinol equivalents
MCT	Medium-chain triglyceride
MCTs	Medium-chain triglycerides
mg/kg	Milligram per kilogram
mg TE	Milligrams tocopherol equivalents
mL	Milliliter
mmol/L	Millimoles per liter
MRLs	Maximum residue limits
µg	Microgram
µg/kg	Micrograms per kilogram
pH	Potential of hydrogen
PDCAAS	Protein Digestibility-Corrected Amino Acid Score
Ppb	Parts per billion
PTWI	Provisional tolerable weekly intake
RMRr	Risk management recommendations
RTH	Ready-to-hang
RTU	Ready-to-use
RUTF	Ready-to-use therapeutic food
SAM	Severe acute malnutrition
SANAS	South African National Accreditation System
WHO	World Health Organization

1. CATEGORY ONE: INFANT FEEDS

1.1. FORMULA FOR PREMATURE INFANTS AND OR LOW BIRTH WEIGHT INFANTS

Description: Formula for premature, very low birth weight, or low birth weight infants. Should contain a minimum of 10% MCTs (of fat content) and whey dominant with a lower lactose content compared to the standard formula.

Indication for use: Sole source of nutrition for premature, very low birth weight infants and low birth weight infants.

NOTE: All formulas must meet the relevant latest Codex Alimentarius standards. Fluoride should not be added to infant formula per the Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants- CODEX STAN 72-1981 with the understanding that tap and packaged water used during the manufacturing process may contain fluoride and should comply with the Regulations relating to all Bottled Waters: Amended, R455 of 26 May 2010, published under the Foodstuffs, Cosmetics, and Disinfectants Act, 1972 (Act No. 54 of 1972). No added probiotics.

Packaging

Item number: RT9-01-001 In 50ml-100ml READY-TO-USE re-sealable plastic screw top bottle

Item number: RT9-01-002 In 400-450g re-sealable tin (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum
Energy (kJ)	267	390
Protein (g)	1.94	3.0
Carbohydrate (g)	6.11	10.0
Fat (g)	3.2	5.4
MCT (g)	>0.27	
Vitamin A (mcg RE)	222.2	666.67
Vitamin D (mcg)	1.26	6.35
Vitamin E (mg TE)	1.22	7.33
Vitamin K (mcg)	2.44	18.67
Vitamin B1 (Thiamine) (mcg)	77.78	193.33
Vitamin B2 (Riboflavin) (mcg)	111.11	286.67
Vitamin B3 (Niacin) (mcg)	611.11	3800
Vitamin B5 (Pantothenic Acid) (mg)	0.33	1.47
Vitamin B6 (Pyridoxine) (mg)	0.039	0.19
Vitamin B7 (Biotin)(mcg)	1.94	10.0
Vitamin B9 (Folic Acid) (mcg)	12.78	66.67
Vitamin B12 (Cobalamin) (mcg)	0.06	0.4
Vitamin C (mg)	9.44	28.67
Calcium (mg)	66.8	133.2
Copper (mcg)	66.67	153.33

Nutritional Composition	Minimum	Maximum
Iodine (mcg)	6.11	36.67
Iron (mg)	1.11	2.0
Magnesium (mg)	5.35	12.15
Phosphorus (mg)	37.89	93.0
Potassium (mg)	49.8	119.6
Selenium (mcg)	3.8	6.7
Sodium (mg)	38.3	76.67
Zinc (mg)	1.11	2.0

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the right to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum
Energy (kJ)	267	390
Protein (g)	1.94	3.0
Carbohydrate (g)	6.11	10.0
Fat (g)	3.2	5.4
MCT (g)	>0.27	
Vitamin A (mcg RE)	222.2	666.67
Vitamin D (mcg)	1.26	6.35
Vitamin E (mg TE)	1.22	7.33
Vitamin K (mcg)	2.44	18.67
Vitamin B1 (Thiamine) (mcg)	77.78	193.33
Vitamin B2 (Riboflavin) (mcg)	111.11	286.67
Vitamin B3 (Niacin) (mcg)	611.11	3800
Vitamin B5 (Pantothenic Acid) (mg)	0.33	1.47
Vitamin B6 (Pyridoxine) (mg)	0.039	0.19
Vitamin B7 (Biotin)(mcg)	1.94	10.0
Vitamin B9 (Folic Acid) (mcg)	12.78	66.67
Vitamin B12 (Cobalamin) (mcg)	0.06	0.4
Vitamin C (mg)	9.44	28.67
Calcium (mg)	66.8	133.2
Copper (mcg)	66.67	153.33
Iodine (mcg)	6.11	36.67
Iron (mg)	1.11	2.0
Magnesium (mg)	5.35	12.15
Phosphorus (mg)	37.89	93.0
Potassium (mg)	49.8	119.6
Selenium (mcg)	3.8	6.7
Sodium (mg)	38.3	76.67
Zinc (mg)	1.11	2.0

Microbiological tests:
The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

1.2. BREASTMILK FORTIFIER FOR PREMATURE AND/OR LOW BIRTH-TO-HANG WEIGHT INFANTS

Description: Breastmilk fortifier for preterm and low birth weight infants.

Indication for Use: For preterm and/or low birth weight infants as per clinical indication.

Packaging
Item number: RT9-01-003 In 1g sachet

Containing per 1g sachet:

Nutritional Composition	Minimum	Maximum
Energy (kJ)		18.27
Protein (g)	0.17	0.36
Carbohydrate (g)		0.58
Fat (g)		0.48
Vitamin A (mcg RE)	48.0	128.78
Vitamin D (mcg)		2.30
Calcium (mg)	15.45	30.75
Iron (mg)	0.36	0.54
Phosphorus (mg)	9.8	18.43
Selenium (mcg)	0.59	1.15
Sodium (mg)	4.5	13.43
Zinc (mg)	0.27	0.46

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum
Energy (kJ)		18.27
Protein (g)	0.17	0.36
Carbohydrate (g)		0.58
Fat (g)		0.48
Vitamin A (mcg RE)	48.0	128.78
Vitamin D (mcg)		2.30
Calcium (mg)	15.45	30.75
Iron (mg)	0.36	0.54

Nutritional Composition	Minimum	Maximum
Phosphorous (mg)	9.8	18.43
Selenium (mcg)	0.59	1.15
Sodium (mg)	4.5	13.43
Zinc (mg)	0.27	0.46

Microbiological tests:
The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

1.3. WHEY DOMINANT INFANT FORMULA

Description: Whey dominant formula for full term infants 0 to 6 months old.

Indication for Use: Infant feed from birth to 6 months of age.

NOTE: All formulas must meet the relevant latest Codex Alimentarius standards. Fluoride should not be added to infant formula per the Standard for Infant formula and Formula for Special Medical Purposes Intended for Infants- CODEX STAN 72-1981 with the understanding that tap and packaged water used during the manufacturing process may contain fluoride and should comply with the Regulations relating to all Bottled Waters: Amended, R455 of 26 May 2010, published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). No added probiotics.

Packaging

Item number:	RT9-01-004	In 50ml-100ml READY-TO-USE resealable plastic screw-top bottle
Item number:	RT9-01-005	In 150ml-200ml READY-TO-USE resealable plastic screw-top bottle
Item number:	RT9-01-006	In 400-450g re-sealable tin (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Whey Protein (g)	>0.66		
Carbohydrate (g)	5.5	9.7	
Fat (g)	2.6	4.1	
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18

Nutritional Composition	Minimum	Maximum	GUL
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin) (mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	
Magnesium (mg)	3.0		10.62
Phosphorus (mg)	15.0		70.8
Potassium (mg)	35.0	126.85	
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	**0.3**		**1.06**

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Whey Protein (g)	>0.66		
Carbohydrate (g)	5.5	9.7	
Fat (g)	2.6	4.1	
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin) (mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	

Nutritional Composition	Minimum	Maximum	GUL
Magnesium (mg)	3.0		10.62
Phosphorus (mg)	15.0		70.8
Potassium (mg)	35.0	126.85	
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	0.3		1.06

Microbiological tests:
The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

1.4. CASEIN DOMINANT INFANT FORMULA

Description: Casein dominant for infants older than 6 months.

Indication for Use: Follow-On Formula for infants aged 6 to 12 months.

NOTE: All formulas must meet the relevant latest Codex Alimentarius standards. Fluoride should not be added to infant formula per the Standard for Infant formula and Formula for Special Medical Purposes Intended for Infants- CODEX STAN 72-1981 with the understanding that tap and packaged water used during the manufacturing process may contain fluoride and should comply with the Regulations relating to all Bottled Waters: Amended, R455 of 26 May 2010, published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). No added probiotics.

Packaging

Item number: RT9-01-007 In 100-200ml READY-TO-USE resealable plastic screw-top bottle
Item number: RT9-01-008 In 200-300ml READY-TO-USE resealable plastic screw-top bottle
Item number: RT9-01-009 In 400g –500g re-sealable tin (include a graded scoop as per reconstituted instructions)
Item number: RT9-01-010 In 800g-1kg re-sealable tin (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Casein Protein (g)	>0.66		
Carbohydrate (g)	5.5	9.70	
Fat (g)	2.75	4.13	
Vitamin A (mcg RE)	45.0	191.7	

Nutritional Composition	Minimum	Maximum	GUL
Vitamin D (mcg)	0.60	2.12	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.40		17.70
Vitamin B1 (Thiamine) (mcg)	35.00		212.4
Vitamin B2 (Riboflavin) (mcg)	47.50		354.0
Vitamin B3 (Niacin) (mcg)	180.0		1059.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	20.0		123.9
Vitamin B7 (Biotin) (mcg)	0.90		7.08
Vitamin B9 (Folic Acid) (mcg)	6.00		35.40
Vitamin B12 (Cobalamin) (mcg)	0.05		1.06
Vitamin C (mg)	6.00		50.15
Calcium (mg)	30.0		126.85
Copper (mcg)	20.0		85.55
Iodine (mcg)	6.00		41.30
Iron (mg)	0.60	1.41	
Magnesium (mg)	3.00		10.62
Phosphorus (mg)	15.00		70.80
Potassium (mg)	35.00	126.85	
Selenium (mcg)	1.20		6.49
Sodium (mg)	12.50	41.30	
Zinc (mg)	0.30		1.06

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Casein Protein (g)	>0.66		
Carbohydrate (g)	5.5	9.70	
Fat (g)	2.75	4.13	
Vitamin A (mcg RE)	45.0	191.7	
Vitamin D (mcg)	0.60	2.12	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.40		17.70
Vitamin B1 (Thiamine) (mcg)	35.00		212.4
Vitamin B2 (Riboflavin) (mcg)	47.50		354.0
Vitamin B3 (Niacin) (mcg)	180.0		1059.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	20.0		123.9
Vitamin B7 (Biotin) (mcg)	0.90		7.08
Vitamin B9 (Folic Acid) (mcg)	6.00		35.40
Vitamin B12 (Cobalamin) (mcg)	0.05		1.06
Vitamin C (mg)	6.00		50.15
Calcium (mg)	30.0		126.85

Nutritional Composition	Minimum	Maximum	GUL
Copper (mcg)	20.0		85.55
Iodine (mcg)	6.00		41.30
Iron (mg)	0.60	1.41	
Magnesium (mg)	3.00		10.62
Phosphorus (mg)	15.00		70.80
Potassium (mg)	35.00	126.85	
Selenium (mcg)	1.20		6.49
Sodium (mg)	12.50	41.30	
Zinc (mg)	0.30		1.06

Microbiological tests:
The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

1.5. ACIDIFIED INFANT FORMULA

Description: An acidified infant formula.

Indication for Use: For infants requiring an acidified feed.

NOTE: All formulas must meet the relevant latest Codex Alimentarius standards. Fluoride should not be added to infant formula per the Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants- CODEX STAN 72-1981 with the understanding that tap and packaged water used during the manufacturing process may contain fluoride and should comply with the Regulations relating to all Bottled Waters: Amended, R455 of 26 May 2010, published under the Foodstuffs, Cosmetics, and Disinfectants Act, 1972 (Act No. 54 of 1972). No added probiotics.

Packaging
Item number: RT9-01-011 In 400g- 500g re-sealable tin (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Carbohydrate (g)	5.5	9.70	
Fat (g)	2.75	4.13	
Vitamin A (mcg RE)	45.0	191.7	
Vitamin D (mcg)	0.60	2.12	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.40		17.70
Vitamin B1 (Thiamine) (mcg)	35.00		212.4
Vitamin B2 (Riboflavin) (mcg)	47.50		354.0

Nutritional Composition	Minimum	Maximum	GUL
Vitamin B3 (Niacin) (mcg)	180.0		1059.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	20.0		123.9
Vitamin B7 (Biotin) (mcg)	0.90		7.08
Vitamin B9 (Folic Acid) (mcg)	6.00		35.40
Vitamin B12 (Cobalamin) (mcg)	0.05		1.06
Vitamin C (mg)	6.00		50.15
Calcium (mg)	30.0		126.85
Copper (mcg)	20.0		85.55
Iodine (mcg)	6.00		41.30
Iron (mg)	0.60	1.41	
Magnesium (mg)	3.00		10.62
Phosphorus (mg)	15.00		70.80
Potassium (mg)	35.00	126.85	
Selenium (mcg)	0.6		6.49
Sodium (mg)	12.50	41.30	
Zinc (mg)	0.30		1.06

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Carbohydrate (g)	5.5	9.70	
Fat (g)	2.75	4.13	
Vitamin A (mcg RE)	45.0	191.7	
Vitamin D (mcg)	0.60	2.12	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.40		17.70
Vitamin B1 (Thiamine) (mcg)	35.00		212.4
Vitamin B2 (Riboflavin) (mcg)	47.50		354.0
Vitamin B3 (Niacin) (mcg)	180.0		1059.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	20.0		123.9
Vitamin B7 (Biotin)(mcg)	0.90		7.08
Vitamin B9 (Folic Acid) (mcg)	6.00		35.40
Vitamin B12 (Cobalamin) (mcg)	0.05		1.06
Vitamin C (mg)	6.00		50.15
Calcium (mg)	30.0		126.85
Copper (mcg)	20.0		85.55
Iodine (mcg)	6.00		41.30
Iron (mg)	0.60	1.41	
Magnesium (mg)	3.00		10.62
Phosphorus (mg)	15.00		70.80
Potassium (mg)	35.00	126.85	

Nutritional Composition	Minimum	Maximum	GUL
Selenium (mcg)	0.6		6.49
Sodium (mg)	12.50	41.30	
Zinc (mg)	0.30		1.06

Microbiological tests:
The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

1.6. ANTI-REGURGITATION/ANTI-REFLUX INFANT FORMULA

Description: Formula containing pre-gelatinized carbohydrate.

Indication for Use: For infants with regurgitation, reflux, or GORD.

NOTE: All formulas must meet the relevant latest Codex Alimentarius standards. Fluoride should not be added to infant formula per the Standard for Infant formula and Formula for Special Medical Purposes Intended for Infants- CODEX STAN 72-1981 with the understanding that tap and packaged water used during the manufacturing process may contain fluoride and should comply with the Regulations relating to all Bottled Waters: Amended, R455 of 26 May 2010, published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). No added probiotics.

Packaging

Item number: RT9-01-012	In 400g – 500g re-sealable tin (include a graded scoop as per reconstituted instructions)
Item number: RT9-01-013	In 800g-1kg re-sealable tin (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Carbohydrate (g)	5.5	9.7	
Fat (g)	2.6	4.1	
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0

Nutritional Composition	Minimum	Maximum	GUL
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin)(mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	
Magnesium (mg)	3.0		10.62
Phosphorus (mg)	15.0		70.8
Potassium (mg)	35.0	126.85	
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	0.3		1.06

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Carbohydrate (g)	5.5	9.7	
Fat (g)	2.6	4.1	
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin)(mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	
Magnesium (mg)	3.0		10.62
Phosphorus (mg)	15.0		70.8
Potassium (mg)	35.0	126.85	

Nutritional Composition	Minimum	Maximum	GUL
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	0.3		1.06

Microbiological tests:
The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

1.7. ENERGY DENSE, HIGH PROTEIN FORMULA FOR INFANTS

Description: High protein feed containing 1kcal/ml.

Indication for Use: Sole source of nutrition, energy dense, whey dominant formula for infants with increased energy and protein requirements.

NOTE: All formulas must meet the relevant latest Codex Alimentarius standards. Fluoride should not be added to infant formula per the Standard for Infant formula and Formula for Special Medical Purposes Intended for Infants- CODEX STAN 72-1981 with the understanding that tap and packaged water used during the manufacturing process may contain fluoride and should comply with the Regulations relating to all Bottled Waters: Amended, R455 of 26 May 2010, published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). No added probiotics.

Packaging

Item number:	RT9-01-014	In 120-200ml READY-TO-USE resealable plastic screw-top bottle
Item number:	RT9-01-015	In 400-500g re-sealable tin(include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	1.90	3.15	
Carbohydrate (g)	9.24	14.85	
Fat (g)	4.41	6.30	
Vitamin A (mcg RE)	58.8	193.5	
Vitamin D (mcg)	1.00	3.24	
Vitamin E (mg TE)	0.50		5.40
Vitamin K (mcg)	4.00		29.25
Vitamin B1 (Thiamine) (mcg)	58.80		324.0
Vitamin B2 (Riboflavin) (mcg)	79.80		540.0
Vitamin B3 (Niacin) (mcg)	294.0		1620.0

Nutritional Composition	Minimum	Maximum	GUL
Vitamin B5 (Pantothenic Acid) (mcg)	403.2		2151.0
Vitamin B6 (Pyridoxine) (mcg)	33.60		202.50
Vitamin B7 (Biotin)(mcg)	1.51		10.80
Vitamin B9 (Folic Acid) (mcg)	10.08		54.00
Vitamin B12 (Cobalamin) (mcg)	0.08		1.62
Vitamin C (mg)	10.08		76.50
Calcium (mg)	50.40		193.50
Copper (mcg)	33.60		130.50
Iodine (mcg)	10.08		63.0
Iron (mg)	0.42	2.16	
Magnesium (mg)	5.04		16.20
Phosphorus (mg)	25.2		108.0
Potassium (mg)	58.8	193.5	
Selenium (mcg)	1.01		9.90
Sodium (mg)	20.16	63.0	
Zinc (mg)	0.50		1.62

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	1.90	3.15	
Carbohydrate (g)	9.24	14.85	
Fat (g)	4.41	6.30	
Vitamin A (mcg RE)	58.8	193.5	
Vitamin D (mcg)	1.00	3.24	
Vitamin E (mg TE)	0.50		5.40
Vitamin K (mcg)	4.00		29.25
Vitamin B1 (Thiamine) (mcg)	58.80		324.0
Vitamin B2 (Riboflavin) (mcg)	79.80		540.0
Vitamin B3 (Niacin) (mcg)	294.0		1620.0
Vitamin B5 (Pantothenic Acid) (mcg)	403.2		2151.0
Vitamin B6 (Pyridoxine) (mcg)	33.60		202.50
Vitamin B7 (Biotin)(mcg)	1.51		10.80
Vitamin B9 (Folic Acid) (mcg)	10.08		54.00
Vitamin B12 (Cobalamin) (mcg)	0.08		1.62
Vitamin C (mg)	10.08		76.50
Calcium (mg)	50.40		193.50
Copper (mcg)	33.60		130.50
Iodine (mcg)	10.08		63.0
Iron (mg)	0.42	2.16	
Magnesium (mg)	5.04		16.20
Phosphorus (mg)	25.2		108.0
Potassium (mg)	58.8	193.5	
Selenium (mcg)	1.01		9.90

Nutritional Composition	Minimum	Maximum	GUL
Sodium (mg)	20.16	63.0	
Zinc (mg)	0.50		1.62

Microbiological tests:
The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

1.8. SOYA BASED FORMULA FOR INFANTS

Description: Formula containing soya protein isolate, galactose free and lactose free for infants 0-6 months

Indication for Use: For infants with galactosaemia.

NOTE: All formulas must meet the relevant latest Codex Alimentarius standards. Fluoride should not be added to infant formula per the Standard for Infant formula and Formula for Special Medical Purposes Intended for Infants- CODEX STAN 72-1981 with the understanding that tap and packaged water used during the manufacturing process may contain fluoride and should comply with the Regulations relating to all Bottled Waters: Amended, R455 of 26 May 2010, published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). No added probiotics.

Packaging

Item number: RT9-01-016	In 400g – 500g re-sealable tin (include a graded scoop as per reconstituted instructions)
Item number: RT9-01-017	In 800g - 900g re-sealable tin (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.3	2.1	
Carbohydrate (g)	5.5	9.7	
Fat (g)	2.6	4.1	
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18

Nutritional Composition	Minimum	Maximum	GUL
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin)(mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	
Magnesium (mg)	3.0		10.62
Phosphorus (mg)	20.0		80.0
Potassium (mg)	35.0	126.85	
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	0.3		1.06

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.3	2.1	
Carbohydrate (g)	5.5	9.7	
Fat (g)	2.6	4.1	
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin)(mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	
Magnesium (mg)	3.0		10.62

Nutritional Composition	Minimum	Maximum	GUL
Phosphorus (mg)	20.0		80.0
Potassium (mg)	35.0	126.85	
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	0.3		1.06

Microbiological tests:
The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

1.9. DISACCHARIDE-FREE FORMULA FOR INFANTS

Description: Disaccharide free (lactose, maltose, and sucrose free), non-soya formula for infants.

Indication for Use: Feed for infants requiring lactose, maltose, and sucrose free, non-soya feeds.

NOTE: All formulas must meet the relevant latest Codex Alimentarius standards. Fluoride should not be added to infant formula per the Standard for Infant formula and Formula for Special Medical Purposes Intended for Infants- CODEX STAN 72-1981 with the understanding that tap and packaged water used during the manufacturing process may contain fluoride and should comply with the Regulations relating to all Bottled Waters: Amended, R455 of 26 May 2010, published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). No added probiotics.

Packaging
Item number: RT9-01-018 In 50ml – 100ml resealable plastic screw-top bottle
Item number: RT9-01-019 In 250-300ml READY-TO-USE resealable plastic screw-top bottle
Item number: RT9-01-020 In 400g- 500g re-sealable tin (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Carbohydrate (g)	5.5	9.7	
Fat (g)	2.6	4.1	
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18

Nutritional Composition	Minimum	Maximum	GUL
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin)(mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	
Magnesium (mg)	3.0		10.62
Phosphorus (mg)	15.0		70.8
Potassium (mg)	35.0	126.85	
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	0.3		1.06

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Carbohydrate (g)	5.5	9.7	
Fat (g)	2.6	4.1	
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin)(mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	
Magnesium (mg)	3.0		10.62

Nutritional Composition	Minimum	Maximum	GUL
Phosphorus (mg)	15.0		70.8
Potassium (mg)	35.0	126.85	
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	0.3		1.06

Microbiological tests:
The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

1.10. ELEMENTAL FORMULA FOR INFANTS

Description: Elemental formula (100% non-allergenic with free amino acids), which is milk protein free, soy protein free, lactose free, sucrose free, gluten free and fructose free.

Indication for Use: Dietary management of severe cow's milk protein allergy, multiple food protein intolerances and other medical conditions where an amino acid-based formula is recommended.

NOTE: All formulas must meet the relevant latest Codex Alimentarius standards. Fluoride should not be added to infant formula per the Standard for Infant formula and Formula for Special Medical Purposes Intended for Infants- CODEX STAN 72-1981 with the understanding that tap and packaged water used during the manufacturing process may contain fluoride and should comply with the Regulations relating to all Bottled Waters: Amended, R455 of 26 May 2010, published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). No added probiotics.

Packaging
Item number: RT9-01-021 — In 400g – 500g re-sealable tin (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Carbohydrate (g)	5.5	9.7	
Fat (g)	2.6	4.1	
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	

Nutritional Composition	Minimum	Maximum	GUL
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin)(mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	
Magnesium (mg)	3.0		10.62
Phosphorus (mg)	15.0		70.8
Potassium (mg)	35.0	126.85	
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	0.3		1.06

Essential Amino acid profile per 100ml	
L-Leucine (mg)	197.0-305.9
L-Lysine (mg)	134.3-223.9
L-Phenylalanine (mg)	65.6-189.6
L-Tryptophan (mg)	34.0-74.6
L-Tyrosine (mg)	82.0-158.2
L-Cysre-sealable tine (mg)	43.2-74.6

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Carbohydrate (g)	5.5	9.7	
Fat (g)	2.6	4.1	
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1

Nutritional Composition	Minimum	Maximum	GUL
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin)(mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	
Magnesium (mg)	3.0		10.62
Phosphorus (mg)	15.0		70.8
Potassium (mg)	35.0	126.85	
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	0.3		1.06

Essential Amino acid profile per 100ml	
L-Leucine (mg)	197.0-305.9
L-Lysine (mg)	134.3-223.9
L-Phenylalanine (mg)	65.6-189.6
L-Tryptophan (mg)	34.0-74.6
L-Tyrosine (mg)	82.0-158.2
L-Cysre-sealable tine (mg)	43.2-74.6

Microbiological tests:
The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

1.11. HIGH MCT CONTAINING INFANT FORMULA

Description: Infant formula, high in MCTs.

Indication for Use: Feed for infants with disturbances of digestion and absorption of LCTs, disturbed bile secretion or pancreatic lipase secretion.

NOTE: All formulas must meet the relevant latest Codex Alimentarius standards. Fluoride should not be added to infant formula per the Standard for Infant formula and Formula for Special Medical Purposes Intended for Infants- CODEX STAN 72-1981 with the understanding that tap and packaged water used during the manufacturing process may contain fluoride and should comply with the Regulations relating to all Bottled Waters: Amended, R455 of 26 May 2010, published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). No added probiotics.

Packaging

Item number: RT9-01-022 In 400g – 500g re-sealable tin (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	355	
Protein (g)	2.0	4.0	
Carbohydrate (g)	5.0	15.0	
Fat (g)	2.0	5.0	
MCT (g)	>1.5		
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin)(mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	
Magnesium (mg)	3.0		10.62
Phosphorus (mg)	15.0		70.8
Potassium (mg)	35.0	126.85	
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	0.3		1.06

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	355	
Protein (g)	2.0	4.0	
Carbohydrate (g)	5.0	15.0	
Fat (g)	2.0	5.0	
MCT (g)	>1.5		

Nutritional Composition	Minimum	Maximum	GUL
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin)(mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	
Magnesium (mg)	3.0		10.62
Phosphorus (mg)	15.0		70.8
Potassium (mg)	35.0	126.85	
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	0.3		1.06

Microbiological tests:
The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

1.12. HYDROLYZED FORMULA FOR INFANTS: WHEY DOMINANT WITH MCT

Description: Hydrolysed whey dominant formula with MCT, lactose free, sucrose free and maltose free.

Indication for Use: Infant formula for the dietary management of malabsorptive conditions, gastrointestinal impairment or severe cow`s milk or soy protein allergies.

NOTE: All formulas must meet the relevant latest Codex Alimentarius standards. Fluoride should not be added to infant formula per the Standard for Infant formula and Formula for Special Medical Purposes Intended for Infants- CODEX STAN 72-1981 with the understanding that tap and packaged water used during the manufacturing process may contain fluoride and should comply with the Regulations relating

to all Bottled Waters: Amended, R455 of 26 May 2010, published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). No added probiotics.

Packaging

Item number: RT9-01-023 In 75ml -100ml resealable plastic READY-TO-USE screw-top bottle
Item number: RT9-01-024 In 200ml-300ml resealable plastic READY-TO-USE screw-top bottle
Item number: RT9-01-025 In 400g-500g re-sealable tin (include a graded scoop as per reconstituted instructions)

Containing per 100ml

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Whey Protein (g)	>0.66		
Carbohydrate (g)	5.5	9.7	
Fat (g)	2.6	4.1	
MCT (g)	>1.0		
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin)(mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	
Magnesium (mg)	3.0		10.62
Phosphorus (mg)	15.0		70.8
Potassium (mg)	35.0	126.85	
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	0.3		1.06

The principal tests listed below must be performed in order to check if the quality of the product meets above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Whey Protein (g)	>0.66		
Carbohydrate (g)	5.5	9.7	
Fat (g)	2.6	4.1	
MCT (g)	>1.0		
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin)(mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	
Magnesium (mg)	3.0		10.62
Phosphorus (mg)	15.0		70.8
Potassium (mg)	35.0	126.85	
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	0.3		1.06

Microbiological tests:
The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

1.13. HYDROLYZED PROTEIN FORMULA FOR ALLERGY WITHOUT MCT

Description: Hydrolysed protein formula without MCT.

Indication for Use: Management of Infants with cow's milk protein allergy.

NOTE: All formulas must meet the relevant latest Codex Alimentarius standards. Fluoride should not be added to infant formula per the Standard for Infant formula and Formula for Special Medical Purposes Intended for Infants- CODEX STAN 72-1981 with the understanding that tap and packaged water used during the manufacturing process may contain fluoride and should comply with the Regulations relating to all Bottled Waters: Amended, R455 of 26 May 2010, published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). No added probiotics.

Packaging

Item number: RT9-01-026 In 200ml-300ml READY-TO-USE resealable plastic screw-top bottle
Item number: RT9-01-027 In 400g- 500g re-sealable tin (include a graded scoop as per reconstituted instructions)
Item number: RT9-01-028 In 800g – 900g container (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Carbohydrate (g)	5.5	9.7	
Fat (g)	2.6	4.1	
MCT (g)	0.0		
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin)(mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	
Magnesium (mg)	3.0		10.62
Phosphorus (mg)	15.0		70.8
Potassium (mg)	35.0	126.85	

Nutritional Composition	Minimum	Maximum	GUL
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	0.3		1.06

The principal tests listed below must be performed in order to check if the quality of the product meets above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Carbohydrate (g)	5.5	9.7	
Fat (g)	2.6	4.1	
MCT (g)	0.0		
Vitamin A (mcg RE)	35.0	126.85	
Vitamin D (mcg)	0.63	1.77	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.50		19.18
Vitamin B1 (Thiamine) (mcg)	35.0		212.40
Vitamin B2 (Riboflavin) (mcg)	47.50		351.0
Vitamin B3 (Niacin) (mcg)	175.0		1062.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	21.30		132.80
Vitamin B7 (Biotin)(mcg)	1.00		7.08
Vitamin B9 (Folic Acid) (mcg)	6.25		35.40
Vitamin B12 (Cobalamin) (mcg)	0.06		1.06
Vitamin C (mg)	6.25		50.15
Calcium (mg)	30.0		103.25
Copper (mcg)	21.25		85.55
Iodine (mcg)	6.25		41.30
Iron (mg)	0.25	1.0	
Magnesium (mg)	3.0		10.62
Phosphorus (mg)	15.0		70.8
Potassium (mg)	35.0	126.85	
Selenium (mcg)	0.60		6.49
Sodium (mg)	12.5	41.3	
Zinc (mg)	0.3		1.06

Microbiological tests:
The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

1.14. PHENYLALANINE-FREE FORMULA

Description: Phenylalanine free infant formula.

Indication for Use: For infants with phenylketonuria and hyperphenylalaninemia.

NOTE: All formulas must meet the relevant latest Codex Alimentarius standards. Fluoride should not be added to infant formula per the Standard for Infant formula and Formula for Special Medical Purposes Intended for Infants- CODEX STAN 72-1981 with the understanding that tap and packaged water used during the manufacturing process may contain fluoride and should comply with the Regulations relating to all Bottled Waters: Amended, R455 of 26 May 2010, published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). No added probiotics.

Packaging

Item number: RT9-01-029 In 400g – 500g re-sealable tin (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Carbohydrate (g)	5.5	9.70	
Fat (g)	2.75	4.13	
Vitamin A (mcg RE)	45.0	191.7	
Vitamin D (mcg)	0.60	2.12	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.40		17.70
Vitamin B1 (Thiamine) (mcg)	35.00		212.4
Vitamin B2 (Riboflavin) (mcg)	47.50		354.0
Vitamin B3 (Niacin) (mcg)	180.0		1059.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	20.0		123.9
Vitamin B7 (Biotin)(mcg)	0.90		7.08
Vitamin B9 (Folic Acid) (mcg)	6.00		35.40
Vitamin B12 (Cobalamin) (mcg)	0.05		1.06
Vitamin C (mg)	6.00		50.15
Calcium (mg)	30.0		126.85
Copper (mcg)	20.0		85.55
Iodine (mcg)	6.00		41.30
Iron (mg)	0.60	1.41	
Magnesium (mg)	3.00		10.62
Phosphorus (mg)	15.00		70.80
Potassium (mg)	35.00	126.85	
Selenium (mcg)	1.20		6.49
Sodium (mg)	12.50	41.30	

Nutritional Composition	Minimum	Maximum	GUL
Zinc (mg)	0.30		1.06

The principal tests listed below must be performed in order to check if the quality of the product meets above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	250	295	
Protein (g)	1.1	2.1	
Carbohydrate (g)	5.5	9.70	
Fat (g)	2.75	4.13	
Vitamin A (mcg RE)	45.0	191.7	
Vitamin D (mcg)	0.60	2.12	
Vitamin E (mg TE)	0.30		3.54
Vitamin K (mcg)	2.40		17.70
Vitamin B1 (Thiamine) (mcg)	35.00		212.4
Vitamin B2 (Riboflavin) (mcg)	47.50		354.0
Vitamin B3 (Niacin) (mcg)	180.0		1059.0
Vitamin B5 (Pantothenic Acid) (mcg)	240.0		1410.1
Vitamin B6 (Pyridoxine) (mcg)	20.0		123.9
Vitamin B7 (Biotin)(mcg)	0.90		7.08
Vitamin B9 (Folic Acid) (mcg)	6.00		35.40
Vitamin B12 (Cobalamin) (mcg)	0.05		1.06
Vitamin C (mg)	6.00		50.15
Calcium (mg)	30.0		126.85
Copper (mcg)	20.0		85.55
Iodine (mcg)	6.00		41.30
Iron (mg)	0.60	1.41	
Magnesium (mg)	3.00		10.62
Phosphorus (mg)	15.00		70.80
Potassium (mg)	35.00	126.85	
Selenium (mcg)	1.20		6.49
Sodium (mg)	12.50	41.30	
Zinc (mg)	0.30		1.06

Microbiological tests:
The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

2. CATEGORY TWO: PAEDIATRIC FEEDS

2.1. PAEDIATRIC FEED THAT CONTAINS 1KCAL/ML

Description: Paediatric lactose-free, gluten-free, fibre free feed that contains 1kcal/ml for children above 1 year.

Indication for Use: For use as a complete feed or supplement for children with increased nutritional requirements or inadequate food intake.

Packaging

Item number:	RT9-02-001	In 200ml - 250 ml READY-TO-USE container (excluding re-tort pouches)
Item number:	RT9-02-002	In 400g - 500g re-sealable container (include a graded scoop as per reconstitution instructions)
Item number:	RT9-02-003	In 400-600ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.0	3.5	
Carbohydrate (g)	10.0	15.0	
Fat (g)	3.5	6.0	
Fibre (g)	-	<0.5	
Vitamin A (mcg RE)	30.0		170.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	0.6		60.0
Vitamin K (mcg)	3.0	6.0	
Vitamin B1 (Thiamine) (mg)	0.05		0.5
Vitamin B2 (Riboflavin) (mg)	0.05		0.5
Vitamin B3 (Niacin) (mg)	0.6		2.0
Vitamin B5 (Pantothenic Acid) (mg)	0.2		1.0
Vitamin B6 (Pyridoxine) (mg)	0.05		6.0
Vitamin B7 (Biotin)(mcg)	0.8		10.0
Vitamin B9 (Folic Acid) (mcg)	9.0		36.0
Vitamin B12 (Cobalamin) (mcg)	0.05		0.5
Vitamin C (mg)	1.5		120.0
Calcium (mg)	70.0		300.0
Copper (mg)	0.03		0.5
Iodine (mcg)	9.0		60.0
Iron (mg)	0.7		4.0
Magnesium (mg)	8.0		35.0
Phosphorus (mg)	46.0		400.0
Potassium (mg)	100.0	250.0	
Selenium (mcg)	2.0		28.0
Sodium (mg)	50.0	120.0	
Zinc (mg)	0.3		2.3

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The

Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.0	3.5	
Carbohydrate (g)	10.0	15.0	
Fat (g)	3.5	6.0	
Fibre (g)	-	<0.5	
Vitamin A (mcg RE)	30.0		170.0
Iron (mg)	0.7		4.0
Potassium (mg)	100.0	250.0	
Sodium (mg)	50.0	120.0	

Microbiological tests:
The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

2.2. PAEDIATRIC FEED THAT CONTAINS 1KCAL/ML WITH FIBRE

Description: Paediatric lactose-free, gluten-free, fibre containing feed that contains 1kcal/ml.

Indication for Use: For use as a complete feed or supplement for children with increased nutritional requirements or inadequate food intake and requiring a fibre-containing feed.

Packaging

Item number:	RT9-02-004	In 200ml - 250 ml READY-TO-USE container (excluding re-tort pouches)
Item number:	RT9-02-005	In 400-500g re-sealable container (include a graded scoop as per reconstitution instructions)
Item number:	RT9-02-006	In 400ml-600ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.0	3.5	
Carbohydrate (g)	10.0	15.0	
Fat (g)	3.5	6.0	
Fibre (g)	0.5	3.0	

Nutritional Composition	Minimum	Maximum	GUL
Vitamin A (mcg RE)	30.0		170.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	0.6		60.0
Vitamin K (mcg)	3.0	6.0	
Vitamin B1 (Thiamine) (mg)	0.05		0.5
Vitamin B2 (Riboflavin) (mg)	0.05		0.5
Vitamin B3 (Niacin) (mg)	0.6		2.0
Vitamin B5 (Pantothenic Acid) (mg)	0.2		1.0
Vitamin B6 (Pyridoxine) (mg)	0.05		6.0
Vitamin B7 (Biotin)(mcg)	0.8		10.0
Vitamin B9 (Folic Acid) (mcg)	9.0		36.0
Vitamin B12 (Cobalamin) (mcg)	0.05		0.5
Vitamin C (mg)	1.5		120.0
Calcium (mg)	70.0		300.0
Copper (mg)	0.03		0.5
Iodine (mcg)	9.0		60.0
Iron (mg)	0.7		4.0
Magnesium (mg)	8.0		35.0
Phosphorus (mg)	46.0		400.0
Potassium (mg)	100.0	250.0	
Selenium (mcg)	2.0		28.0
Sodium (mg)	50.0	120.0	
Zinc (mg)	0.3		2.3

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.0	3.5	
Carbohydrate (g)	10.0	15.0	
Fat (g)	3.5	6.0	
Fibre (g)	0.5	3.0	
Vitamin A (mcg RE)	30.0		170.0
Iron (mg)	0.7		4.0
Potassium (mg)	100.0	250.0	
Sodium (mg)	50.0	120.0	

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

2.3. HIGH ENERGY FEED WITHOUT FIBRE PROVIDING 1.5KCAL/ML

Description: High energy feed without fibre that provides 1,5kcal/ml. Gluten and lactose free.

Indication for Use: Feed for paediatric with increased energy requirements.

Packaging

Item number: RT9-02-007 In 200ml - 300ml READY-TO-USE container (excluding re-tort pouches)
Item number: RT9-02-008 In 400-500g re-sealable container (include a graded scoop as per reconstituted instructions)
Item number: RT9-02-009 In 400-600ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	600	660	
Protein (g)	3.0	5.0	
Carbohydrate (g)	15.0	20.0	
Fat (g)	5.0	10.0	
Fibre (g)	-	<0.5	
Vitamin A (mcg RE)	30.0		170.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	0.6		60.0
Vitamin K (mcg)	3.0	6.0	
Vitamin B1 (Thiamine) (mg)	0.05		0.5
Vitamin B2 (Riboflavin) (mg)	0.05		0.5
Vitamin B3 (Niacin) (mg)	0.6		2.0
Vitamin B5 (Pantothenic Acid) (mg)	0.2		1.0
Vitamin B6 (Pyridoxine) (mg)	0.05		6.0
Vitamin B7 (Biotin)(mcg)	0.8		10.0
Vitamin B9 (Folic Acid) (mcg)	9.0		36.0
Vitamin B12 (Cobalamin) (mcg)	0.05		0.5
Vitamin C (mg)	1.5		120.0
Calcium (mg)	70.0		300.0
Copper (mg)	0.03		0.5
Iodine (mcg)	9.0		60.0
Iron (mg)	0.7		4.0
Magnesium (mg)	8.0		35.0
Phosphorus (mg)	46.0		400.0
Potassium (mg)	100.0	250.0	
Selenium (mcg)	2.0		28.0
Sodium (mg)	50.0	120.0	
Zinc (mg)	0.3		2.3

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The

Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	600	660	
Protein (g)	3.0	5.0	
Carbohydrate (g)	15.0	20.0	
Fat (g)	5.0	10.0	
Fibre (g)	-	<0.5	
Vitamin A (mcg RE)	30.0		170.0
Iron (mg)	0.7		4.0
Potassium (mg)	100.0	250.0	
Sodium (mg)	50.0	120.0	

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

2.4. HIGH ENERGY FEED WITH FIBRE PROVIDING 1.5KCAL/ML

Description: High Energy, lactose free and gluten free feed with fibre that provides 1,5kcal/ml.

Indication for Use: Feed for paediatric patients with higher energy requirements.

Packaging

Item number: RT9-02-010 In 200ml – 250ml READY-TO-USE container (excluding re-tort pouches)
Item number: RT9-02-011 In 400-600ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	600	660	
Protein (g)	3.0	5.0	
Carbohydrate (g)	15.0	20.0	
Fat (g)	5.0	10.0	
Fibre (g)	0.5	3.0	
Vitamin A (mcg RE)	30.0		170.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	0.6		60.0
Vitamin K (mcg)	3.0	6.0	
Vitamin B1 (Thiamine) (mg)	0.05		0.5
Vitamin B2 (Riboflavin) (mg)	0.05		0.5
Vitamin B3 (Niacin) (mg)	0.6		2.0

Nutritional Composition	Minimum	Maximum	GUL
Vitamin B5 (Pantothenic Acid) (mg)	0.2		1.0
Vitamin B6 (Pyridoxine) (mg)	0.05		6.0
Vitamin B7 (Biotin)(mcg)	0.8		10.0
Vitamin B9 (Folic Acid) (mcg)	9.0		36.0
Vitamin B12 (Cobalamin) (mcg)	0.05		0.5
Vitamin C (mg)	1.5		120.0
Calcium (mg)	70.0		300.0
Copper (mg)	0.03		0.5
Iodine (mcg)	9.0		60.0
Iron (mg)	0.7		4.0
Magnesium (mg)	8.0		35.0
Phosphorus (mg)	46.0		400.0
Potassium (mg)	100.0	250.0	
Selenium (mcg)	2.0		28.0
Sodium (mg)	50.0	120.0	
Zinc (mg)	0.3		2.3

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	600	660	
Protein (g)	3.0	5.0	
Carbohydrate (g)	15.0	20.0	
Fat (g)	5.0	10.0	
Fibre (g)	0.5	3.0	
Vitamin A (mcg RE)	30.0		170.0
Iron (mg)	0.7		4.0
Potassium (mg)	100.0	250.0	
Sodium (mg)	50.0	120.0	

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

2.5. SEMI-ELEMENTAL FEED FOR PAEDIATRICS

Description: Semi-elemental feed that provides 1 kcal/ml with a protein source from peptides and fat source that includes MCT. Must be lactose and gluten free.

Indication for Use: Dietary management of conditions related to malabsorption and maldigestion (short bowel syndrome, inflammatory bowel disease, chronic gastroenteritis).

Packaging

Item number: RT9-02-012 In 200ml – 300ml READY-TO-USE container (excluding re-tort pouches)
Item number: RT9-02-013 In 400g -500g re-sealable container (include a graded scoop as per reconstituted instructions)
Item number: RT9-02-014 In 400-600ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.0	3.5	
Carbohydrate (g)	10.0	15.0	
Fat (g)	3.5	6.0	
Medium Chain Triglycerides (g)	1.5	3.0	
Vitamin A (mcg RE)	30.0		170.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	0.6		60.0
Vitamin K (mcg)	3.0	6.0	
Vitamin B1 (Thiamine) (mg)	0.05		0.5
Vitamin B2 (Riboflavin) (mg)	0.05		0.5
Vitamin B3 (Niacin) (mg)	0.6		2.0
Vitamin B5 (Pantothenic Acid) (mg)	0.2		1.0
Vitamin B6 (Pyridoxine) (mg)	0.05		6.0
Vitamin B7 (Biotin)(mcg)	0.8		10.0
Vitamin B9 (Folic Acid) (mcg)	9.0		36.0
Vitamin B12 (Cobalamin) (mcg)	0.05		0.5
Vitamin C (mg)	1.5		120.0
Calcium (mg)	70.0		300.0
Copper (mg)	0.03		0.5
Iodine (mcg)	9.0		60.0
Iron (mg)	0.7		4.0
Magnesium (mg)	8.0		35.0
Phosphorus (mg)	46.0		400.0
Potassium (mg)	100.0	250.0	
Selenium (mcg)	2.0		28.0
Sodium (mg)	50.0	120.0	
Zinc (mg)	0.3		2.3

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.0	3.5	
Carbohydrate (g)	10.0	15.0	
Fat (g)	3.5	6.0	
Medium Chain Triglycerides (MCT)	1.5	3.0	
Vitamin A (mcg RE)	30.0		170.0
Iron (mg)	0.7		4.0
Potassium (mg)	100.0	250.0	
Sodium (mg)	50.0	120.0	

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

2.6. HIGH NITROGEN HIGH ENERGY SEMI-ELEMENTAL FEED FOR PAEDIATRICS

Description: High nitrogen, high energy, semi-elemental feed that provides 1.5 kcal/ml with a protein source from peptides and fat source that includes MCT. Must be lactose and gluten free.

Indication for Use: For children with malabsorption, pancreatitis, short bowel syndrome, Bowel fistula, and small bowel feeding.

Packaging
Item number: RT9-02-015 In 500ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	600	660	
Protein (g)	3.0	5.0	
Carbohydrate (g)	15.0	20.0	
Fat (g)	5.0	10.0	
Medium Chain Triglycerides (g)	2.5	5.0	
Vitamin A (mcg RE)	30.0		170.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	0.6		60.0
Vitamin K (mcg)	3.0	6.0	
Vitamin B1 (Thiamine) (mg)	0.05		0.5
Vitamin B2 (Riboflavin) (mg)	0.05		0.5
Vitamin B3 (Niacin) (mg)	0.6		2.0
Vitamin B5 (Pantothenic Acid) (mg)	0.2		1.0

Vitamin B6 (Pyridoxine) (mg)	0.05		6.0
Vitamin B7 (Biotin)(mcg)	0.8		10.0
Vitamin B9 (Folic Acid) (mcg)	9.0		36.0
Vitamin B12 (Cobalamin) (mcg)	0.05		0.5
Vitamin C (mg)	1.5		120.0
Calcium (mg)	70.0		300.0
Copper (mg)	0.03		0.5
Iodine (mcg)	9.0		60.0
Iron (mg)	0.7		4.0
Magnesium (mg)	8.0		35.0
Phosphorus (mg)	46.0		400.0
Potassium (mg)	100.0	250.0	
Selenium (mcg)	2.0		28.0
Sodium (mg)	50.0	120.0	
Zinc (mg)	0.3		2.3

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	600	660	
Protein (g)	3.0	5.0	
Carbohydrate (g)	15.0	20.0	
Fat (g)	5.0	10.0	
Medium Chain Triglycerides (MCT) (g)	2.5	5.0	
Vitamin A (mcg RE)	30.0		170.0
Iron (mg)	0.7		4.0
Potassium (mg)	100.0	250.0	
Sodium (mg)	50.0	120.0	

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

2.7. AMINO-ACID BASED FEED FOR PAEDIATRICS

Description: Paediatric elemental feed (100% non-allergenic with free amino acids and nucleotides), or children over 1 year of age, which is milk protein free, soy protein free, lactose free, sucrose free, gluten free and fructose free.

Indication for Use: For paediatrics with cow's Milk Protein allergy, sensitivity to intact protein, gastroesophageal reflux, short bowel syndrome, protracted intractable diarrhoea, eosinophilic oesophagitis, and other medical conditions where an amino acid-based feed is required.

Packaging
Item number: RT9-02-016 In 400g-500g re-sealable -container (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.0	3.5	
Carbohydrate (g)	10.0	15.0	
Fat (g)	3.5	6.0	
Vitamin A (mcg RE)	30.0		170.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	0.6		60.0
Vitamin K (mcg)	3.0	6.0	
Vitamin B1 (Thiamine) (mg)	0.05		0.5
Vitamin B2 (Riboflavin) (mg)	0.05		0.5
Vitamin B3 (Niacin) (mg)	0.6		2.0
Vitamin B5 (Pantothenic Acid) (mg)	0.2		1.0
Vitamin B6 (Pyridoxine) (mg)	0.05		6.0
Vitamin B7 (Biotin)(mcg)	0.8		10.0
Vitamin B9 (Folic Acid) (mcg)	9.0		36.0
Vitamin B12 (Cobalamin) (mcg)	0.05		0.5
Vitamin C (mg)	1.5		120.0
Calcium (mg)	70.0		300.0
Copper (mg)	0.03		0.5
Iodine (mcg)	9.0		60.0
Iron (mg)	0.7		4.0
Magnesium (mg)	8.0		35.0
Phosphorus (mg)	46.0		400.0
Potassium (mg)	100.0	250.0	
Selenium (mcg)	2.0		28.0
Sodium (mg)	50.0	120.0	
Zinc (mg)	0.3		2.3

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The

Department of Health reserves the right to request additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein Equivalent (g)	2.0	3.5	
Carbohydrate (g)	10.0	15.0	
Fat (g)	3.5	6.0	
Vitamin A (mcg RE)	30.0		170.0
Iron (mg)	0.7		4.0
Potassium (mg)	100.0	250.0	
Sodium (mg)	50.0	120.0	

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

2.8. FEED FOR THE TREATMENT OF INTRACTABLE (DRUG-RESISTANT) EPILEPSY

Description: High fat (>70%) feed for paediatric patients.

Indication for Use: Feed for paediatrics (1-10 years) with drug resistant epilepsy, Pyruvate dehydrogenase (E1) deficiency, Glucose transporter 1 deficiency syndrome, to be used as a supplement or sole source of nutrition.

Packaging

Item number: RT9-02-017 In 300 -400g re-sealable container (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	>1.5		
Carbohydrate (g)		≤1.0	
Fat (g)	8.0	10.7	
Vitamin A (mcg RE)	30.0		170.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	0.6		60.0
Vitamin K (mcg)	3.0	6.0	
Vitamin B1 (Thiamine) (mg)	0.05		0.5

Nutritional Composition	Minimum	Maximum	GUL
Vitamin B2 (Riboflavin) (mg)	0.05		0.5
Vitamin B3 (Niacin) (mg)	0.6		2.0
Vitamin B5 (Pantothenic Acid) (mg)	0.2		1.0
Vitamin B6 (Pyridoxine) (mg)	0.05		6.0
Vitamin B7 (Biotin)(mcg)	0.8		10.0
Vitamin B9 (Folic Acid) (mcg)	9.0		36.0
Vitamin B12 (Cobalamin) (mcg)	0.05		0.5
Vitamin C (mg)	1.5		120.0
Calcium (mg)	70.0		300.0
Copper (mg)	0.03		0.5
Iodine (mcg)	9.0		60.0
Iron (mg)	0.7		4.0
Magnesium (mg)	8.0		35.0
Phosphorus (mg)	46.0		400.0
Potassium (mg)	100.0	250.0	
Selenium (mcg)	2.0		28.0
Sodium (mg)	50.0	120.0	
Zinc (mg)	0.3		2.3

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein Equivalent (g)	>1.5		
Carbohydrate (g)		≤1.0	
Fat (g)	8.0	10.7	
Vitamin A (mcg RE)	30.0		170.0
Iron (mg)	0.7		4.0
Potassium (mg)	100.0	250.0	
Sodium (mg)	50.0	120.0	

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3. CATEGORY THREE: ADULT FEEDS

3.1. ENTERAL FEED WITHOUT FIBRE PROVIDING 1KCAL/ML

Description: Lactose-free, gluten free and fibre free feed that contains 1kcal/ml.

Indication for Use: Feed for adults with increased requirements or an inadequate food intake.

Packaging

Item number: RT9-03-001 In 200ml - 300 ml READY-TO-USE container (excluding re-tort pouches)
Item number: RT9-03-002 In 300g - 500g re-sealable container (include a graded scoop as per reconstituted instructions)
Item number: RT9-03-003 In 1000 ml READY-TO-HANG container
Item number: RT9-03-004 1kg re-sealable container (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.5	5.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	1.5	5.0	
Fibre (g)	-	<1.0	
Vitamin A (mcg RE)	46.67		200.0
Vitamin D (mcg)	1.0		6.67
Vitamin E (mg TE)	1.0		66.67
Vitamin K (mcg)	5.0	8.0	
Vitamin B1 (Thiamine) (mg)	0.07	0.5	
Vitamin B2 (Riboflavin) (mg)	0.07	0.5	
Vitamin B3 (Niacin) (mg)	0.93		2.33
Vitamin B5 (Pantothenic Acid) (mg)	0.33	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.08		6.67
Vitamin B7 (Biotin)(mcg)	1.67	6.0	
Vitamin B9 (Folic Acid) (mcg)	16.0		40.0
Vitamin B12 (Cobalamin) (mcg)	0.16	1.0	
Vitamin C (mg)	4.33		133.33
Calcium (mg)	60.0		200.0
Copper (mg)	0.06		0.67
Iodine (mcg)	8.0		73.3
Iron (mg)	0.53		3.0
Magnesium (mg)	13.0	28.0	
Phosphorus (mg)	46.67		266.67
Potassium (mg)	120.0	226.67	
Selenium (mcg)	3.67		26.67
Sodium (mg)	40.0		153.33
Zinc (mg)	0.53		2.67

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The

Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.5	5.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	1.5	5.0	
Fibre (g)	-	<1.0	
Vitamin A (mcg RE)	46.67		200.0
Iron (mg)	0.53		3.0
Potassium (mg)	120.0	226.67	
Sodium (mg)	40.0		153.33

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.2. ENTERAL FEED WITH FIBRE PROVIDING 1KCAL/ML

Description: Lactose free, gluten free, 1kcal/ml feed, containing fibre

Indication for Use: Feed for adults with increased requirements, or an inadequate food intake, and requiring fibre.

Packaging

Item number: RT9-03-005 In 200ml – 300ml READY-TO-USE container (excluding re-tort pouches)
Item number: RT9-03-006 In 400g – 500g re-sealable container (include a graded scoop as per reconstituted instructions)
Item number: RT9-03-007 In 1000 ml READY-TO-HANG container
Item number: RT9-03-008 In 1kg re-sealable container (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.5	5.0	
Carbohydrate (g)	10.0	20.0	

Nutritional Composition	Minimum	Maximum	GUL
Fat (g)	1.5	5.0	
Fibre (g)	1.0	4.0	
Vitamin A (mcg RE)	46.67		200.0
Vitamin D (mcg)	1.0		6.67
Vitamin E (mg TE)	1.0		66.67
Vitamin K (mcg)	5.0	8.0	
Vitamin B1 (Thiamine) (mg)	0.07	0.5	
Vitamin B2 (Riboflavin) (mg)	0.07	0.5	
Vitamin B3 (Niacin) (mg)	0.93		2.33
Vitamin B5 (Pantothenic Acid) (mg)	0.33	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.08		6.67
Vitamin B7 (Biotin)(mcg)	1.67	6.0	
Vitamin B9 (Folic Acid) (mcg)	16.0		40.0
Vitamin B12 (Cobalamin) (mcg)	0.16	1.0	
Vitamin C (mg)	4.33		133.33
Calcium (mg)	60.0		200.0
Copper (mg)	0.06		0.67
Iodine (mcg)	8.0		73.3
Iron (mg)	0.53		3.0
Magnesium (mg)	13.0	28.0	
Phosphorus (mg)	46.67		266.67
Potassium (mg)	120.0	226.67	
Selenium (mcg)	3.67		26.67
Sodium (mg)	40.0		153.33
Zinc (mg)	0.53		2.67

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.5	5.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	1.5	5.0	
Fibre (g)	1.0	4.0	
Vitamin A (mcg RE)	46.67		200.0
Iron (mg)	0.53		3.0
Potassium (mg)	120.0	226.67	
Sodium (mg)	40.0		153.33

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.3. MODERATE ENERGY, MODERATE PROTEIN, LOW LACTOSE FEED WITHOUT FIBRE

Description: Moderate energy, moderate protein feed, that provides 1.2-1.5kcal/ml, without fibre.

Indication for Use: For patients with increased energy and protein requirements, requiring a fibre-free feed.

Packaging

Item number:	RT9-03-009	In 200ml – 300ml READY-TO-USE container (excluding re-tort pouches)
Item number:	RT9-03-010	In 500ml READY-TO-HANG container
Item number:	RT9-03-011	In 1000ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	5.0	10.0	
Carbohydrate (g)	10.0	20.0	
Fibre (g)	-	<1.0	
Fat (g)	4.0	7.0	
Vitamin A (mcg RE)	70.0		300.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	1.5		100.0
Vitamin K (mcg)	7.5	12.0	
Vitamin B1 (Thiamine) (mg)	0.1	0.5	
Vitamin B2 (Riboflavin) (mg)	0.1	0.5	
Vitamin B3 (Niacin) (mg)	1.0		3.5
Vitamin B5 (Pantothenic Acid) (mg)	0.5	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		10.0
Vitamin B7 (Biotin)(mcg)	2.5	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		60.0
Vitamin B12 (Cobalamin) (mcg)	0.20	1.0	
Vitamin C (mg)	5.0		200.0
Calcium (mg)	60.0		300.0
Copper (mg)	0.09		1.0
Iodine (mcg)	8.0		110.0
Iron (mg)	0.8		4.5
Magnesium (mg)	13.0	42.0	
Phosphorus (mg)	50.0		400.0
Potassium (mg)	100.0	340.0	
Selenium (mcg)	5.0		40.0
Sodium (mg)	40.0		230.0
Zinc (mg)	0.8		4.0

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The

Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	5.0	10.0	
Carbohydrate (g)	10.0	20.0	
Fibre (g)	-	<1.0	
Fat (g)	4.0	7.0	
Vitamin A (mcg RE)	70.0		300.0
Iron (mg)	0.8		4.5
Potassium (mg)	100.0	340.0	
Sodium (mg)	40.0		230.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.4. MODERATE ENERGY, MODERATE PROTEIN, LOW LACTOSE ENTERAL FEED WITH FIBRE

Description: Moderate energy, moderate protein feed, that provides 1.2-1.5kcal/ml, containing fibre.

Indication for Use: For patients with increased energy and protein requirements based on a 1.2-1.5kcal/ml fibre containing feed.

Packaging

Item number:	RT9-03-012	In 200ml – 300ml READY-TO-USE container (excluding re-tort pouches)
Item number:	RT9-03-013	In 500ml READY-TO-HANG container
Item number:	RT9-03-014	In 1000ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	5.0	10.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	4.0	7.0	
Fibre (g)	1.0	4.0	
Vitamin A (mcg RE)	70.0		300.0

Nutritional Composition	Minimum	Maximum	GUL
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	1.5		100.0
Vitamin K (mcg)	7.5	12.0	
Vitamin B1 (Thiamine) (mg)	0.1	0.5	
Vitamin B2 (Riboflavin) (mg)	0.1	0.5	
Vitamin B3 (Niacin) (mg)	1.0		3.5
Vitamin B5 (Pantothenic Acid) (mg)	0.5	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		10.0
Vitamin B7 (Biotin)(mcg)	2.5	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		60.0
Vitamin B12 (Cobalamin) (mcg)	0.20	1.0	
Vitamin C (mg)	5.0		200.0
Calcium (mg)	60.0		300.0
Copper (mg)	0.09		1.0
Iodine (mcg)	8.0		110.0
Iron (mg)	0.8		4.5
Magnesium (mg)	13.0	42.0	
Phosphorus (mg)	50.0		400.0
Potassium (mg)	100.0	340.0	
Selenium (mcg)	5.0		40.0
Sodium (mg)	40.0		230.0
Zinc (mg)	0.8		4.0

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	5.0	10.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	4.0	7.0	
Fibre (g)	1.0	4.0	
Vitamin A (mcg RE)	70.0		300.0
Iron (mg)	0.8		4.5
Potassium (mg)	100.0	340.0	
Sodium (mg)	40.0		230.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.5. HIGH ENERGY HIGH PROTEIN FEED WITHOUT FIBRE

Description: High-energy, high protein, lactose free feed without fibre that contains 1.5kcal/ml to 2kcal/ml.

Indication for Use: Feed for acutely ill or chronic catabolic disease and fluid restricted patients without fibre.

Packaging

Item number: RT9-03-015 In 200ml-300ml container (excluding re-tort pouches)
Item number: RT9-03-016 In 500ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	630	840	
Protein (g)	10.0	15.0	
Carbohydrate (g)	15.0	30.0	
Fibre (g)	-	<1.0	
Fat (g)	7.0	10.0	
Vitamin A (mcg RE)	70.0		300.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	1.5		100.0
Vitamin K (mcg)	7.5	12.0	
Vitamin B1 (Thiamine) (mg)	0.1	0.5	
Vitamin B2 (Riboflavin) (mg)	0.1	0.5	
Vitamin B3 (Niacin) (mg)	1.0		3.5
Vitamin B5 (Pantothenic Acid) (mg)	0.5	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		10.0
Vitamin B7 (Biotin)(mcg)	2.5	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		60.0
Vitamin B12 (Cobalamin) (mcg)	0.20	1.0	
Vitamin C (mg)	5.0		200.0
Calcium (mg)	60.0		300.0
Copper (mg)	0.09		1.0
Iodine (mcg)	8.0		110.0
Iron (mg)	0.8		4.5
Magnesium (mg)	13.0	42.0	
Phosphorus (mg)	50.0		400.0
Potassium (mg)	100.0	340.0	
Selenium (mcg)	5.0		40.0
Sodium (mg)	40.0		230.0
Zinc (mg)	0.8		4.0

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The

Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	630	840	
Protein (g)	10.0	15.0	
Carbohydrate (g)	15.0	30.0	
Fibre (g)	-	<1.0	
Fat (g)	7.0	10.0	
Vitamin A (mcg RE)	70.0		300.0
Iron (mg)	0.8		4.5
Potassium (mg)	100.0	340.0	
Sodium (mg)	40.0		230.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.6. HIGH ENERGY HIGH PROTEIN FEED WITH FIBRE

Description: High-energy, high protein, lactose free feed with fibre that contains 1.5kcal/ml up to 2kcal/ml.

Indication for Use: Feed for acutely ill or chronic catabolic disease and fluid restricted patients with fibre.

Packaging
Item number: RT9-03-017 In 200ml-300ml container (excluding re-tort pouches)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	630	840	
Protein (g)	10.0	15.0	
Carbohydrate (g)	15.0	30.0	
Fat (g)	7.0	10.0	
Fibre (g)	1.0	4.0	
Vitamin A (mcg RE)	70.0		300.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	1.5		100.0
Vitamin K (mcg)	7.5	12.0	
Vitamin B1 (Thiamine) (mg)	0.1	0.5	
Vitamin B2 (Riboflavin) (mg)	0.1	0.5	

Nutritional Composition	Minimum	Maximum	GUL
Vitamin B3 (Niacin) (mg)	1.0		3.5
Vitamin B5 (Pantothenic Acid) (mg)	0.5	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		10.0
Vitamin B7 (Biotin)(mcg)	2.5	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		60.0
Vitamin B12 (Cobalamin) (mcg)	0.20	1.0	
Vitamin C (mg)	5.0		200.0
Calcium (mg)	60.0		300.0
Copper (mg)	0.09		1.0
Iodine (mcg)	8.0		110.0
Iron (mg)	0.8		4.5
Magnesium (mg)	13.0	42.0	
Phosphorus (mg)	50.0		400.0
Potassium (mg)	100.0	453.3	
Selenium (mcg)	5.0		40.0
Sodium (mg)	40.0		230.0
Zinc (mg)	0.8		4.0

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	630	840	
Protein (g)	10.0	15.0	
Carbohydrate (g)	15.0	30.0	
Fat (g)	7.0	10.0	
Fibre (g)	1.0	4.0	
Vitamin A (mcg RE)	70.0		300.0
Iron (mg)	0.8		4.5
Potassium (mg)	100.0	453.3	
Sodium (mg)	40.0		230.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.7. STANDARD SEMI-ELEMENTAL FEED CONTAINING MCTs

Description: Semi-elemental, low residue lactose-free feed with MCTs that contains 1kcal/ml.

Indication for Use: Feed for the critically ill patients presenting with malabsorption.

Packaging

Item number: RT9-03-018 In 200ml – 300ml READY-TO-USE container (excluding re-tort pouches)
Item no: RT9-03-019 In 400g – 500g re-sealable container (include a graded scoop as per reconstituted instructions)
Item no: RT9-03-020 In 500ml READY-TO-HANG container
Item no: RT9-03-021 In 1000ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.5	5.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	1.5	5.0	
Medium Chain Triglycerides (MCT) (g)	0.5	3.0	
Vitamin A (mcg RE)	46.67		200.0
Vitamin D (mcg)	1.0		6.67
Vitamin E (mg TE)	1.0		66.67
Vitamin K (mcg)	5.0	8.0	
Vitamin B1 (Thiamine) (mg)	0.07	0.5	
Vitamin B2 (Riboflavin) (mg)	0.07	0.5	
Vitamin B3 (Niacin) (mg)	0.93		2.33
Vitamin B5 (Pantothenic Acid) (mg)	0.33	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.08		6.67
Vitamin B7 (Biotin)(mcg)	1.67	6.0	
Vitamin B9 (Folic Acid) (mcg)	16.0		40.0
Vitamin B12 (Cobalamin) (mcg)	0.16	1.0	
Vitamin C (mg)	4.33		133.33
Calcium (mg)	60.0		200.0
Copper (mg)	0.06		0.67
Iodine (mcg)	8.0		73.3
Iron (mg)	0.53		3.0
Magnesium (mg)	13.0	28.0	
Phosphorus (mg)	46.67		266.67
Potassium (mg)	120.0	226.67	
Selenium (mcg)	3.67		26.67
Sodium (mg)	40.0		153.33
Zinc (mg)	0.53		2.67

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.5	5.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	1.5	5.0	
Medium Chain Triglycerides (MCT) (g)	0.5	3.0	
Vitamin A (mcg RE)	46.67		200.0
Iron (mg)	0.53		3.0
Potassium (mg)	120.0	226.67	
Sodium (mg)	40.0		153.33

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.8. MODERATE ENERGY, MODERATE PROTEIN SEMI-ELEMENTAL FEED CONTAINING MCTs

Description: Moderate energy, moderate protein, lactose and gluten-free semi-elemental feed with MCTs that contains 1.2 to 1.5kcal/ml.

Indication for Use: Moderate energy, moderate protein feed used for patients with malabsorption and fluid restrictions.

Packaging
Item no: RT9-03-022 In 500ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	5.0	10.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	4.0	7.0	
Medium Chain Triglycerides (MCT) (g)	1.5	4.0	
Vitamin A (mcg RE)	70.0		300.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	1.5		100.0
Vitamin K (mcg)	7.5	12.0	
Vitamin B1 (Thiamine) (mg)	0.1	0.5	
Vitamin B2 (Riboflavin) (mg)	0.1	0.5	
Vitamin B3 (Niacin) (mg)	1.0		3.5

Nutritional Composition	Minimum	Maximum	GUL
Vitamin B5 (Pantothenic Acid) (mg)	0.5	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		10.0
Vitamin B7 (Biotin)(mcg)	2.5	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		60.0
Vitamin B12 (Cobalamin) (mcg)	0.20	1.0	
Vitamin C (mg)	5.0		200.0
Calcium (mg)	60.0		300.0
Copper (mg)	0.09		1.0
Iodine (mcg)	8.0		110.0
Iron (mg)	0.8		4.5
Magnesium (mg)	13.0	42.0	
Phosphorus (mg)	50.0		400.0
Potassium (mg)	100.0	340.0	
Selenium (mcg)	5.0		40.0
Sodium (mg)	40.0		230.0
Zinc (mg)	0.8		4.0

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	5.0	10.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	4.0	7.0	
Medium Chain Triglycerides (MCT) (g)	1.5	4.0	
Vitamin A (mcg RE)	70.0		300.0
Iron (mg)	0.8		4.5
Potassium (mg)	100.0	340.0	
Sodium (mg)	40.0		230.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.9. LOW SODIUM FEED

Description: Low sodium feed providing 1kcal/ml.

Indication for Use: For patients with hypernatremia.

Packaging

Item no:	RT9-03-023	In 200-250ml container (excluding re-tort pouches)
Item no:	RT9-03-024	In 1000ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.5	5.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	1.5	5.0	
Vitamin A (mcg RE)	46.67		200.0
Vitamin D (mcg)	1.0		6.67
Vitamin E (mg TE)	1.0		66.67
Vitamin K (mcg)	5.0	8.0	
Vitamin B1 (Thiamine) (mg)	0.07	0.5	
Vitamin B2 (Riboflavin) (mg)	0.07	0.5	
Vitamin B3 (Niacin) (mg)	0.93		2.33
Vitamin B5 (Pantothenic Acid) (mg)	0.33	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.08		6.67
Vitamin B7 (Biotin)(mcg)	1.67	6.0	
Vitamin B9 (Folic Acid) (mcg)	16.0		40.0
Vitamin B12 (Cobalamin) (mcg)	0.16	1.0	
Vitamin C (mg)	4.33		133.33
Calcium (mg)	60.0		200.0
Copper (mg)	0.06		0.67
Iodine (mcg)	8.0		73.3
Iron (mg)	0.53		3.0
Magnesium (mg)	13.0	28.0	
Phosphorus (mg)	46.67		266.67
Potassium (mg)	120.0	226.67	
Selenium (mcg)	3.67		26.67
Sodium (mg)		≤40.0	
Zinc (mg)	0.53		2.67

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.5	5.0	

Nutritional Composition	Minimum	Maximum	GUL
Carbohydrate (g)	10.0	20.0	
Fat (g)	1.5	5.0	
Vitamin A (mcg RE)	46.67		200.0
Iron (mg)	0.53		3.0
Potassium (mg)	120.0	226.67	
Sodium (mg)		≤40.0	

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.10. STANDARD TO MODERATE ENERGY AND PROTEIN, CLEAR FLUID, HIGH CARBOHYDRATE, FAT FREE AND FIBRE FREE FEED

Description: Clear fluid, lactose free, fat free, fibre free, high carbohydrate, with standard to moderate energy and protein.

Indication for Use: Patients with malabsorption and/or fat restriction.

Packaging
Item no: RT9-03-025 In 200ml – 300ml container (excluding re-tort pouches)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	630	
Protein (g)	2.5	10.0	
Carbohydrate (g)	10.0	40.0	
Fibre (g)	-	<1.0	
Fat (g)	0	-	-
Vitamin A (mcg RE)			≤200.0
Vitamin D (mcg)			≤6.67
Vitamin E (mg TE)			≤66.67
Vitamin K (mcg)		≤8.0	
Vitamin B1 (Thiamine) (mg)		≤0.5	
Vitamin B2 (Riboflavin) (mg)		≤0.5	
Vitamin B3 (Niacin) (mg)			≤2.33
Vitamin B5 (Pantothenic Acid) (mg)		≤1.5	
Vitamin B6 (Pyridoxine) (mg)			≤6.67
Vitamin B7 (Biotin)(mcg)		≤6.0	
Vitamin B9 (Folic Acid) (mcg)			≤40.0

Nutritional Composition	Minimum	Maximum	GUL
Vitamin B12 (Cobalamin) (mcg)		≤1.0	
Vitamin C (mg)			≤133.33
Calcium (mg)			≤200.0
Copper (mg)			≤0.67
Iodine (mcg)			≤73.3
Iron (mg)			≤3.0
Magnesium (mg)		≤28.0	
Phosphorus (mg)			≤266.67
Potassium (mg)		≤226.67	
Selenium (mcg)			≤26.67
Sodium (mg)			≤153.33
Zinc (mg)			≤2.67

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	630	
Protein (g)	2.5	10.0	
Carbohydrate (g)	10.0	40.0	
Fibre (g)	-	<1.0	
Fat (g)	0	-	

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.11. CLEAR FLUID, CONTAINING CARBOHYDRATE, BUT FAT FREE, PROTEIN FREE AND FIBRE FREE FEED

Description: Isotonic clear fluid, that is fat, fibre and protein free, containing carbohydrate.

Indication for Use: For pre-operative management of surgical patients.

Packaging

Item no: RT9-03-026 In 200ml-300ml container (excluding re-tort pouches)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	170	255	
Protein (g)	0	-	
Carbohydrate (g)	10.0	15.0	
Fibre (g)	-	<1.0	
Fat (g)	0	-	-
Phosphorus (mg)			≤266.67
Potassium (mg)		≤226.67	
Sodium (mg)			≤153.33

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	170	255	
Protein (g)	0	-	
Carbohydrate (g)	10.0	15 .0	
Fibre (g)	-	<1.0	
Fat (g)	0	-	

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.12. STANDARD FEED FOR IMPAIRED GLUCOSE TOLERANCE

Description: Lactose free feed with fibre and chromium suitable for patients with impaired glucose tolerance

Indication for Use: Feed/supplement for patients with impaired glucose tolerance.

Packaging

Item no: RT9-03-027 In 200ml – 300ml READY-TO-USE container (excluding re-tort pouches)
Item no: RT9-03-028 In 400g – 500g re-sealable container (include a graded scoop as per reconstituted instructions)
Item no: RT9-03-029 In 500ml READY-TO-HANG container
Item no: RT9-03-030 In 1000ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.5	5.0	
Carbohydrate (g)	8.0	20.0	
Fat (g)	1.5	5.9	
Fibre (g)	1.0	4.0	
Vitamin A (mcg RE)	46.67		200.0
Vitamin D (mcg)	1.0		6.67
Vitamin E (mg TE)	1.0		66.67
Vitamin K (mcg)	5.0	8.0	
Vitamin B1 (Thiamine) (mg)	0.07	0.5	
Vitamin B2 (Riboflavin) (mg)	0.07	0.5	
Vitamin B3 (Niacin) (mg)	0.93		2.33
Vitamin B5 (Pantothenic Acid) (mg)	0.33	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.08		6.67
Vitamin B7 (Biotin)(mcg)	1.67	6.0	
Vitamin B9 (Folic Acid) (mcg)	16.0		40.0
Vitamin B12 (Cobalamin) (mcg)	0.16	1.0	
Vitamin C (mg)	4.33		133.33
Calcium (mg)	60.0		200.0
Chromium (mcg)	13.33		66.67
Copper (mg)	0.06		0.67
Iodine (mcg)	8.0		73.3
Iron (mg)	0.53		3.0
Magnesium (mg)	13.0	28.0	
Phosphorus (mg)	46.67		266.67
Potassium (mg)	120.0	340.0	
Selenium (mcg)	3.67		26.67
Sodium (mg)	40.0		153.33
Zinc (mg)	0.53		2.67

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.5	5.0	
Carbohydrate (g)	8.0	20.0	
Fat (g)	1.5	5.9	
Fibre (g)	1.0	4.0	
Vitamin A (mcg RE)	46.67		200.0
Chromium (mcg)	13.33		66.67
Iron (mg)	0.53		3.0
Potassium (mg)	120.0	340.0	
Sodium (mg)	40.0		153.33

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.13. MODERATE ENERGY AND MODERATE PROTEIN FEED FOR PATIENTS WITH IMPAIRED GLUCOSE TOLERANCE

Description: Moderate energy and moderate protein lactose free feed with fibre and chromium suitable for patients with impaired glucose tolerance.

Indication for Use: For patients with impaired glucose tolerance that are hyper-catabolic and require increased energy and protein.

Packaging

Item number:	RT9-03-031	In 200-250ml container (excluding re-tort pouches)
Item number:	RT9-03-032	In 500ml READY-TO-HANG container
Item number:	RT9-03-033	In 1000ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	5.0	10.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	4.0	7.0	
Fibre (g)	1.0	4.0	
Vitamin A (mcg RE)	70.0		300.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	1.5		100.0
Vitamin K (mcg)	7.5	12.0	
Vitamin B1 (Thiamine) (mg)	0.1	0.5	
Vitamin B2 (Riboflavin) (mg)	0.1	0.5	
Vitamin B3 (Niacin) (mg)	1.0		3.5
Vitamin B5 (Pantothenic Acid) (mg)	0.5	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		10.0
Vitamin B7 (Biotin)(mcg)	2.5	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		60.0
Vitamin B12 (Cobalamin) (mcg)	0.20	1.0	
Vitamin C (mg)	5.0		200.0
Calcium (mg)	60.0		300.0

Nutritional Composition	Minimum	Maximum	GUL
Chromium (mcg)	10.0		100.0
Copper (mg)	0.09		1.0
Iodine (mcg)	8.0		110.0
Iron (mg)	0.8		4.5
Magnesium (mg)	13.0	42.0	
Phosphorus (mg)	50.0		400.0
Potassium (mg)	100.0	340.0	
Selenium (mcg)	5.0		40.0
Sodium (mg)	40.0		230.0
Zinc (mg)	0.8		4.0

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	5.0	10.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	4.0	7.0	
Fibre (g)	1.0	4.0	
Vitamin A (mcg RE)	70.0		300.0
Chromium (mcg)	10.0		100.0
Iron (mg)	0.8		4.5
Potassium (mg)	100.0	340.0	
Sodium (mg)	40.0		230.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.14. VERY HIGH ENERGY, MODERATE PROTEIN FEED FOR PATIENTS WITH KIDNEY DISEASE REQUIRING DIALYSIS

Description: Very high energy (1.5-2.5kCal/ml), very low electrolyte feed used for patients requiring dialysis with fluid restrictions.

Indication for Use: Enteral feed for patients with kidney disease requiring dialysis.

Packaging

Item number: RT9-03-034 In 200ml – 250ml READY-TO-USE container (excluding re-tort pouches)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	630	1050	
Protein (g)	5.0	10.0	
Carbohydrate (g)	10.0	25.0	
Fat (g)	7.0	15.0	
Vitamin A (mcg RE)	70.0		300.0
Vitamin D (mcg)	1.5		10.0
Vitamin E natural (mg TE)	1.5		90.0
Vitamin K (mcg)	7.5	12.0	
Vitamin B1 (Thiamine) (mg)	0.1	0.5	
Vitamin B2 (Riboflavin) (mg)	0.1	0.5	
Vitamin B3 (Niacin) (mg)	1.0		3.5
Vitamin B5 (Pantothenic Acid) (mg)	0.5	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		10.0
Vitamin B7 (Biotin)(mcg)	2.5	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		100.0
Vitamin B12 (Cobalamin) (mcg)	0.20	1.0	
Vitamin C (mg)	5.0	20.0	
Calcium (mg)			<300
Copper (mg)	0.09		1.0
Iodine (mcg)	8.0		110.0
Iron (mg)	0.8		4.5
Magnesium (mg)	13.0	42.0	
Phosphorus (mg)		<100.0	
Potassium (mg)		<300.0	
Selenium (mcg)	5.0		40.0
Sodium (mg)			<153.33
Zinc (mg)	0.8		4.0

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the right to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	630	1050	
Protein (g)	5.0	10.0	
Carbohydrate (g)	10.0	25.0	
Fat (g)	7.0	15.0	
Calcium (mg)			<300.0
Iron (mg)	0.8		4.5
Phosphorus (mg)		<100.0	
Potassium (mg)		<300.0	
Sodium (mg)			<153.33

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.15. STANDARD FEED FOR INFLAMMATORY BOWEL DISEASE

Description: Polymeric feed with MCTs. Fibre, lactose, and gluten free.

Indication for Use: Feed for inflammatory bowel disease.

Packaging

Item number: RT9-03-035 In 400g-500g re-sealable container (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.5	5.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	1.5	5.0	
Medium Chain Triglycerides (MCT) (g)	0.5	3.0	
Fibre (g)	-	0.0	
Vitamin A (mcg RE)	46.67		200.0
Vitamin D (mcg)	1.0		6.67
Vitamin E (mg TE)	1.0		66.67
Vitamin K (mcg)	5.0	8.0	
Vitamin B1 (Thiamine) (mg)	0.07	0.5	
Vitamin B2 (Riboflavin) (mg)	0.07	0.5	
Vitamin B3 (Niacin) (mg)	0.93		2.33
Vitamin B5 (Pantothenic Acid) (mg)	0.33	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.08		6.67
Vitamin B7 (Biotin)(mcg)	1.67	6.0	
Vitamin B9 (Folic Acid) (mcg)	16.0		40.0
Vitamin B12 (Cobalamin) (mcg)	0.16	1.0	
Vitamin C (mg)	4.33		133.33
Calcium (mg)	60.0		200.0
Copper (mg)	0.06		0.67
Iodine (mcg)	8.0		73.3

Nutritional Composition	Minimum	Maximum	GUL
Iron (mg)	0.53		3.0
Magnesium (mg)	13.0	28.0	
Phosphorus (mg)	46.67		266.67
Potassium (mg)	120.0	266.67	
Selenium (mcg)	3.67		26.67
Sodium (mg)	-		<153.33
Zinc (mg)	0.53		2.67

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	418	450	
Protein (g)	2.5	5.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	1.5	5.0	
Medium Chain Triglycerides (MCT) (g)	0.5	3.0	
Fibre (g)	-	0.0	
Vitamin A (mcg RE)	46.67		200.0
Iron (mg)	0.53		3.0
Potassium (mg)	120.0	266.67	
Sodium (mg)	-		<153.33

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.16. FEED FOR ONCOLOGY PATIENTS

Description: High energy, moderate protein, high fat, fibre containing feed with EPA.

Indication for Use: For oncology patients requiring a high fat, low carbohydrate feed, with EPA.

Packaging

Item no:	RT9-03-036	In 200-250ml container (excluding re-tort pouches)
Item no:	RT9-03-037	In 500ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	630	840	
Protein (g)	5.0	10.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	4.0	7.0	
EPA (g)	0.2	0.7	
Fibre (g)	1.0	4.0	
Vitamin A (mcg RE)	70.0		300.0
Vitamin D (mcg)	1.5	6.0	
Vitamin E (mg TE)	1.5		100.0
Vitamin K (mcg)	7.5	12.0	
Vitamin B1 (Thiamine) (mg)	0.1	0.5	
Vitamin B2 (Riboflavin) (mg)	0.1	0.5	
Vitamin B3 (Niacin) (mg)	1.0		3.5
Vitamin B5 (Pantothenic Acid) (mg)	0.5	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		10.0
Vitamin B7 (Biotin)(mcg)	2.5	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		60.0
Vitamin B12 (Cobalamin) (mcg)	0.20	1.0	
Vitamin C (mg)	5.0		200.0
Calcium (mg)	60.0		300.0
Copper (mg)	0.09		1.0
Iodine (mcg)	8.0		110.0
Iron (mg)	0.8		4.5
Magnesium (mg)	13.0	42.0	
Phosphorus (mg)	70.0		400.0
Potassium (mg)	120.0	340.0	
Selenium (mcg)	6.0	15.0	
Sodium (mg)	40.0		230.0
Zinc (mg)	0.8		4.0

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	630	840	
Protein (g)	5.0	10.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	4.0	7.0	
EPA (g)	0.2	0.7	
Fibre (g)	1.0	4.0	
Vitamin A (mcg RE)	70.0		300.0
Iron (mg)	0.8		4.5
Potassium (mg)	120.0	340.0	
Sodium (mg)	40.0		230.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.17. RESTRICTED ENERGY MODERATE PROTEIN FEED WITH FIBRE

Description: Restricted energy, moderate protein feed with fibre that contains <1kcal/ml.

Indication for Use: For patients requiring restricted energy and moderate protein with fibre.

Packaging

Item no: RT9-03-038 In 50-60g powder sachet

Item no: RT9-03-039 In 1000ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	315	400	
Protein (g)	5.0	10.0	
Carbohydrate (g)	5.0	10.0	
Fat (g)	-	<3.0	
Fibre (g)	1.0	4.0	
Vitamin A (mcg RE)	70.0		300.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	1.5		100.0
Vitamin K (mcg)	7.5	12.0	
Vitamin B1 (Thiamine) (mg)	0.07	0.5	
Vitamin B2 (Riboflavin) (mg)	0.07	0.5	
Vitamin B3 (Niacin) (mg)	1.0		3.5
Vitamin B5 (Pantothenic Acid) (mg)	0.5	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		10.0
Vitamin B7 (Biotin)(mcg)	2.5	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		60.0
Vitamin B12 (Cobalamin) (mcg)	0.2	1.0	
Vitamin C (mg)	5.0		200.0
Calcium (mg)	60.0		300.0
Copper (mg)	0.09		1.0
Iodine (mcg)	8.0		110.0
Iron (mg)	0.8		4.5
Magnesium (mg)	13.0	42.0	
Phosphorus (mg)	50.0		400.0
Potassium (mg)	100.0	340.0	

Nutritional Composition	Minimum	Maximum	GUL
Selenium (mcg)	5.0		40.0
Sodium (mg)	40.0		230.0
Zinc (mg)	0.8		4.0

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	315	400	
Protein (g)	5.0	10.0	
Carbohydrate (g)	5.0	10.0	
Fat (g)		<3.0	
Fibre (g)	1.0	4.0	
Vitamin A (mcg RE)	70.0		300.0
Iron (mg)	0.8		4.5
Potassium (mg)	100.0	340.0	
Sodium (mg)	40.0		230.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.18. MODERATE ENERGY MODERATE PROTEIN FEED WITH HYROLYSED WHEY

Description: Moderate energy, moderate protein feed with hydrolysed whey.

Indication for Use: For critically ill patients requiring a moderate protein and moderate energy feed.

Packaging

Item no:	RT9-03-040	In 500ml READY-TO-HANG Container
Item no:	RT9-03-041	In 1000ml READY-TO-HANG Container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	5.0	10.0	

Nutritional Composition	Minimum	Maximum	GUL
Carbohydrate (g)	10.0	20.0	
Fat (g)	3.5	7.0	
Vitamin A (mcg RE)	70.0		300.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	1.5		100.0
Vitamin K (mcg)	7.5	12.0	
Vitamin B1 (Thiamine) (mg)	0.1	0.5	
Vitamin B2 (Riboflavin) (mg)	0.1	0.5	
Vitamin B3 (Niacin) (mg)	1.0		3.5
Vitamin B5 (Pantothenic Acid) (mg)	0.5	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		10.0
Vitamin B7 (Biotin)(mcg)	2.5	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		60.0
Vitamin B12 (Cobalamin) (mcg)	0.20	1.0	
Vitamin C (mg)	5.0		200.0
Calcium (mg)	60.0		300.0
Copper (mg)	0.09		1.0
Iodine (mcg)	8.0		110.0
Iron (mg)	0.8		4.5
Magnesium (mg)	13.0	42.0	
Phosphorus (mg)	50.0		400.0
Potassium (mg)	100.0	340.0	
Selenium (mcg)	5.0		40.0
Sodium (mg)	40.0		230.0
Zinc (mg)	0.8		4.0

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	5.0	10.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	3.5	7.0	
Vitamin A (mcg RE)	70.0		300.0
Iron (mg)	0.8		4.5
Potassium (mg)	100.0	340.0	
Sodium (mg)	40.0		230.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.19. VERY HIGH ENERGY, MODERATELY HIGH PROTEIN SUPPLEMENT WITHOUT FIBRE

Description: Feed for adults with increased calories that contains >2kcal/ml, moderately high in protein and fibre free.

Indication for Use: Feed for patients with increased requirements who are fluid restricted or unable to tolerate large volumes orally.

Packaging

Item no: RT9-03-042 In 100-150ml READY-TO-USE container (excluding re-tort pouches)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	>840		
Protein (g)	10.0	20.0	
Carbohydrate (g)	15.0	30.0	
Fibre (g)		<1.0	
Fat (g)	7.0	20.0	
Vitamin A (mcg RE)	93.3		400.0
Vitamin D (mcg)	2.0	13.3	
Vitamin E (mg TE)	2.0	133.3	
Vitamin K (mcg)	10.0	16.0	
Vitamin B1 (Thiamine) (mg)	0.1	0.5	
Vitamin B2 (Riboflavin) (mg)	0.1	0.5	
Vitamin B3 (Niacin) (mg)	1.0		4.7
Vitamin B5 (Pantothenic Acid) (mg)	0.7	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		13.3
Vitamin B7 (Biotin)(mcg)	3.3	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		80.0
Vitamin B12 (Cobalamin) (mcg)	0.20	1.0	
Vitamin C (mg)	5.0		266.0
Calcium (mg)	60.0		400.0
Copper (mg)	0.1		1.3
Iodine (mcg)	8.0		146.7
Iron (mg)	1.1		6.0
Magnesium (mg)	13.0	56.0	
Phosphorus (mg)	50.0		533.3
Potassium (mg)	100.0	453.3	
Selenium (mcg)	5.0	53.3	
Sodium (mg)	10.0		230.0
Zinc (mg)	1.1		5.3

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	>840		
Protein (g)	10.0	20.0	
Carbohydrate (g)	15.0	30.0	
Fibre (g)		<1.0	
Fat (g)	7.0	20.0	
Vitamin A (mcg RE)	93.3		400.0
Iron (mg)	1.1		6.0
Potassium (mg)	100.0	453.3	
Sodium (mg)	10.0		230.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.20. MODERATE ENERGY, MODERATE PROTEIN SUPPLEMENT WITHOUT FIBRE FOR WOUND HEALING

Description: Moderate energy and protein, supplement without fibre, containing Arginine, Vitamin C and Zinc

Indication for Use: For the dietary management of pressure ulcers and chronic wounds

Packaging

Item no: RT9-03-043 In 35-50g sachet

Item no: RT9-03-044 In 150 -200ml READY-TO-USE container (excluding re-tort pouches)

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	5.0	10.0	
Arginine (g)	1.5	3.0	
Glutamine (g)		≤3.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	3.0	10.0	
Fibre		<1.0	
Vitamin A (mcg RE)	70.0		300.0

Nutritional Composition	Minimum	Maximum	GUL
Vitamin D (mcg)	2.0	13.3	
Vitamin E (mg TE)	2.0	133.3	
Vitamin K (mcg)	10.0	16.0	
Vitamin B1 (Thiamine) (mg)	0.1	0.5	
Vitamin B2 (Riboflavin) (mg)	0.1	0.5	
Vitamin B3 (Niacin) (mg)	1.0		3.5
Vitamin B5 (Pantothenic Acid) (mg)	0.5	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		10.0
Vitamin B7 (Biotin)(mcg)	2.5	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		60.0
Vitamin B12 (Cobalamin) (mcg)	0.20	1.0	
Vitamin C (mg)	50		200.0
Calcium (mg)	60.0		300.0
Copper (mg)	0.09		1.0
Iodine (mcg)	8.0		110.0
Iron (mg)	0.8		4.5
Magnesium (mg)	13.0	42.0	
Phosphorus (mg)	50.0		400.0
Potassium (mg)	100.0	340.0	
Selenium (mcg)	5.0	40.0	
Sodium (mg)	40.0		230.0
Zinc (mg)	4.1		18.9

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	5.0	10.0	
Arginine (g)	1.5	3.0	
Glutamine (g)		≤3.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	3.0	10.0	
Fibre		<1.0	
Vitamin A (mcg RE)	70.0		300.0
Vitamin C (mg)	50.0		200.0
on (mg)	0.8		4.5
Potassium (mg)	100.0	340.0	
Sodium (mg)	40.0		230.0
Zinc (mg)	4.1		18.9

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.21. MODERATE ENERGY AND MODERATE PROTEIN FEED CONTAINING GLUTAMINE

Description: Moderate energy, moderate protein complete feed containing glutamine and lactose free.
Indication for Use: For the critically ill patient at risk of malabsorption with burns, severe trauma, head-and-neck cancer, post gastrointestinal surgery and patients with moderate to high output fistulas.

Packaging
Item Number: RT9-03-045 In 500ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	5.0	10.0	
Glutamine (g)	1.5	2.5	
Carbohydrate (g)	10.0	20.0	
Fat (g)	4.0	7.0	
Vitamin A (mcg RE)	70.0		300.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	1.5		100.0
Vitamin K (mcg)	7.5	12.0	
Vitamin B1 (Thiamine) (mg)	0.1	0.5	
Vitamin B2 (Riboflavin) (mg)	0.1	0.5	
Vitamin B3 (Niacin) (mg)	1.0		3.5
Vitamin B5 (Pantothenic Acid) (mg)	0.5	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		10.0
Vitamin B7 (Biotin)(mcg)	2.5	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		60.0
Vitamin B12 (Cobalamin) (mcg)	0.20	1.0	
Vitamin C (mg)	5.0		200.0
Calcium (mg)	60.0		300.0
Copper (mg)	0.09		1.0
Iodine (mcg)	8.0		110.0
Iron (mg)	0.8		4.5
Magnesium (mg)	13.0	42.0	
Phosphorus (mg)	50.0		400.0
Potassium (mg)	100.0	340.0	
Selenium (mcg)	5.0		40.0
Sodium (mg)	40.0		230.0
Zinc (mg)	0.8		4.0

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	5.0	10.0	
Glutamine (g)	1.5	2.5	
Carbohydrate (g)	10.0	20.0	
Fat (g)	4.0	7.0	
Vitamin A (mcg RE)	70.0		300.0
Iron (mg)	0.8		4.5
Potassium (mg)	100.0	340.0	
Sodium (mg)	40.0		230.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.22. STANDARD TO HIGH ENERGY AND HIGH PROTEIN IMMUNO-MODULATORY SUPPLEMENT

Description: Supplement with immune modulatory properties, enriched with arginine, and omega-3 fatty acids from fish oil.

Indications for Use: Adult patients requiring an immune-modulatory supplement for pre/peri or post-operative.

Packaging

Item no: RT9-03-046 In 150– 300ml READY-TO-USE container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	340	840	
Protein (g)	10.0	15.0	
Arginine (g)	1.0		3.0
Carbohydrate (g)	7.0	18.0	
Fat (g)	1.5	7.0	
Omega 3 fatty acids (g)	0.2		5.0
Vitamin A (mcg RE)	70.0		300.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	1.5		100.0
Vitamin K (mcg)	7.5	12.0	
Vitamin B1 (Thiamine) (mg)	0.1	0.5	
Vitamin B2 (Riboflavin) (mg)	0.1	0.5	
Vitamin B3 (Niacin) (mg)	1.0		10.0

Nutritional Composition	Minimum	Maximum	GUL
Vitamin B5 (Pantothenic Acid) (mg)	0.5	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		10.0
Vitamin B7 (Biotin)(mcg)	2.5	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		60.0
Vitamin B12 (Cobalamin) (mcg)	0.2	1.0	
Vitamin C (mg)	5.0		200.0
Calcium (mg)	60.0		300.0
Copper (mg)	0.09		1.0
Iodine (mcg)	8.0		110.0
Iron (mg)	0.8		4.5
Magnesium (mg)	13.0	42.0	
Phosphorus (mg)	50.0		400.0
Potassium (mg)	100.0	340.0	
Selenium (mcg)	5.0		40.0
Sodium (mg)	40.0		230.0
Zinc (mg)	0.8		4.0

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	340	840	
Protein (g)	10.0	15.0	
Arginine (g)	1.0		3.0
Carbohydrate (g)	7.0	18. 0	
Fat (g)	1.5	7.0	
Omega 3 fatty acids	0.2		5.0
Vitamin A (mcg RE)	70.0		300.0
Iron (mg)	0.8		4.5
Potassium (mg)	100.0	340.0	
Sodium (mg)	40.0		230.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.23. HIGH ENERGY MODERATE PROTEIN SEMI ELEMENTAL IMMUNO-MODULATORY FEED

Description: High Energy, moderately high protein, semi-elemental feed containing MCTs, and enriched with omega-3 fatty acids from fish oil.

Indications for Use: For adult patients with malabsorption, requiring an immuno-modulatory feed.

Packaging
Item no: RT9-03-047 In 500ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	630	840	
Protein (g)	5.0	10.0	
Carbohydrate (g)	10.0	30.0	
Fat (g)	4.0	10.0	
Medium Chain Triglyceride (MCT) (g)	1.5	4.0	
Omega 3 fatty acids (g)	0.2	0.5	
Vitamin A (mcg RE)	70.0		300.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	1.5		100.0
Vitamin K (mcg)	7.5	12.0	
Vitamin B1 (Thiamine) (mg)	0.1	0.5	
Vitamin B2 (Riboflavin) (mg)	0.1	0.5	
Vitamin B3 (Niacin) (mg)	1.0		3.5
Vitamin B5 (Pantothenic Acid) (mg)	0.5	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		10.0
Vitamin B7 (Biotin)(mcg)	2.5	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		60.0
Vitamin B12 (Cobalamin) (mcg)	0.20	1.0	
Vitamin C (mg)	5.0		200.0
Calcium (mg)	60.0		300.0
Copper (mg)	0.09		1.0
Iodine (mcg)	8.0		110.0
Iron (mg)	0.8		4.5
Magnesium (mg)	13.0	42.0	
Phosphorus (mg)	50.0		400.0
Potassium (mg)	100.0	340.0	
Selenium (mcg)	5.0		40.0
Sodium (mg)	40.0		230.0
Zinc (mg)	0.8		4.0

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	630	840	
Protein (g)	5.0	10.0	
Carbohydrate (g)	10.0	30.0	
Fat (g)	4.0	10.0	
Medium Chain Triglyceride (MCT) (g)	1.5	4.0	
Omega 3 fatty acids (g)	0.2	0.5	
Vitamin A (mcg RE)	70.0		300.0
Iron (mg)	0.8		4.5
Potassium (mg)	100.0	340.0	
Sodium (mg)	40.0		230.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

3.24. MODERATE ENERGY STANDARD PROTEIN FEED CONTAINING MCT OIL AND BRANCHED CHAIN AMINO ACIDS

Description: Feed with at least 40% of fat as medium chain triglycerides (MCT), and 40 % of protein as branched chain amino acids (BCAA) and low in aromatic amino acids and sodium.

Indication for Use: An adult feed for patients with acute and chronic liver diseases to be used as sole source of nutrition or as supplement.

Packaging
Item number: RT9-03-048 In 500ml READY-TO-HANG container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	2.5	5.0	
Branched Chain Amino Acids (BCAA) (g)	1.0	3.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	4.0	7.0	
Medium Chain Triglycerides (MCT) (g)	≥1.6		
Vitamin A (mcg RE)	70.0		400.0
Vitamin D (mcg)	1.5		10.0
Vitamin E (mg TE)	1.5		100.0
Vitamin K (mcg)	7.5	12.0	

Nutritional Composition	Minimum	Maximum	GUL
Vitamin B1 (Thiamine) (mg)	0.1	0.5	
Vitamin B2 (Riboflavin) (mg)	0.1	0.5	
Vitamin B3 (Niacin) (mg)	1.0		3.5
Vitamin B5 (Pantothenic Acid) (mg)	0.5	1.5	
Vitamin B6 (Pyridoxine) (mg)	0.1		10.0
Vitamin B7 (Biotin)(mcg)	2.5	20.0	
Vitamin B9 (Folic Acid) (mcg)	20.0		60.0
Vitamin B12 (Cobalamin) (mcg)	0.2	1.0	
Vitamin C (mg)	5.0		200.0
Calcium (mg)	60.0		300.0
Copper (mg)	0.09		1.0
Iodine (mcg)	8.0		110.0
Iron (mg)	0.8		4.0
Magnesium (mg)	13.0	42.0	
Phosphorus (mg)	50.0		400.0
Potassium (mg)	100.0	340.0	
Selenium (mcg)	5.0		40.0
Sodium (mg)	40.0		230.0
Zinc (mg)	0.8		4.5

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum	GUL
Energy (kJ)	500	630	
Protein (g)	2.5	5.0	
Branched Chain Amino Acids (BCAA) (g)	1.0	3.0	
Carbohydrate (g)	10.0	20.0	
Fat (g)	4.0	7.0	
Medium Chain Triglycerides (MCT) (g)	≥1.6		
Vitamin A (mcg RE)	70.0		400.0
Iron (mg)	0.8		4.5
Potassium (mg)	100.0	340.0	
Sodium (mg)	40.0		230.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

4. CATEGORY FOUR: MODULAR FEEDS

4.1. CARBOHYDRATE SUPPLEMENT

Description: Long-chain carbohydrate polymer supplement. The supplement must be easily dissolvable in fluids and must not enhance the sweetness of food.

Indication for Use: An energy supplement for patients who are unable to meet their energy requirements from regular dietary intake.

Packaging

Item no: RT9-04-001 In 400 -500g re-sealable container (include a graded scoop as per reconstituted instructions)

Containing per 100g:

Nutritional Composition	Minimum	Maximum
Energy (kJ)	1360	2040
Carbohydrate (g)	80	120
Sodium (mg)		≤130

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum
Energy (kJ)	1360	2040
Carbohydrate (g)	80	120
Sodium (mg)		≤130

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

4.2. FAT AND CARBOHYDRATE SUPPLEMENT

Description: Supplement blend of fat and carbohydrates. The product must be easily dissolvable in fluids and not affect the sweetness or taste of food.

Indication for Use: supplement for patients who are unable to meet their energy requirements from regular dietary intake.

Packaging

Item no: RT9-04-002 In 400g-500g re-sealable container (include a graded scoop as per reconstituted instructions)

Containing per 100g:

Nutritional Composition	Minimum	Maximum
Energy (kJ)	1950	2990
Carbohydrate (g)	70	120
Fat (g)	20	25
Sodium (mg)		≤130

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum
Energy (kJ)	1950	2990
Carbohydrate (g)	70	120
Fat (g)	20	25
Sodium (mg)		≤130

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

4.3. CASEIN BASED PROTEIN SUPPLEMENT

Description: Casein based, low-electrolyte protein supplement. The supplement must be easily dissolvable in fluids and could be added to foods as well. The supplement must be unflavoured.

Indication for Use: For patients with increased protein needs.

Packaging

Item no: RT9-04-003 In 150g – 300g re-sealable container (include a graded scoop as per reconstituted instructions)

Containing per 100g:

Nutritional Composition	Minimum	Maximum
Energy (kJ)	1000	2000
Protein (g)	70	100
Casein (g)	>50	
Carbohydrate (g)		<5
Fat (g)		<2
Calcium (mg)		≤1600
Phosphorus (mg)		≤850
Potassium (mg)		≤150
Sodium (mg)		≤140

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum
Energy (kJ)	1000	2000
Protein (g)	70	100
Casein (g)	>50	
Carbohydrate (g)		<5
Fat (g)		<2
Calcium (mg)		≤1600
Phosphorus (mg)		≤850
Potassium (mg)		≤150
Sodium (mg)		≤140

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

4.4. WHEY DOMINANT PROTEIN SUPPLEMENT

Description: Whey isolate protein supplement easily dissolvable in fluids.

Indication for Use: Protein supplement to be used where enteral feeds or food do not meet the full protein requirements.

Packaging

Item number: RT9-04-004 In 5-10g sachet
Item number: RT9-04-005 In 200-400g re-sealable container (include a graded scoop as per reconstituted instructions)

Containing per 100g:

Nutritional Composition	Minimum	Maximum
Energy (kJ)	1000	2225
Protein (g)	70	100
Whey (g)	70	100
Carbohydrate (g)		<20
Fat (g)		<5
Calcium (mg)		≤1600
Phosphorus (mg)		≤1000
Potassium (mg)		≤800
Sodium (mg)		≤140

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum
Energy (kJ)	1000	2225
Protein (g)	70	100
Whey (g)	70	100
Carbohydrate (g)		<20
Fat (g)		<5
Calcium (mg)		≤1600
Phosphorus (mg)		≤1000
Potassium (mg)		≤800
Sodium (mg)		≤140

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

4.5. LIQUID PROTEIN SUPPLEMENT

Description: Liquid protein for tube feeding

Indication for Use: For the dietary management of patients on a tube feed requiring added protein

Packaging
Item number: RT9-04-006 In 30-50ml container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum
Energy (kJ)		<1100
Protein (g)	25	60
Carbohydrate (g)		<5
Fat (g)		<5
Calcium (mg)		<160
Phosphorus (mg)		<300
Potassium (mg)		<200
Sodium (mg)		≤140

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum
Energy (kJ)		<1100
Protein (g)	25	60
Carbohydrate (g)		<5
Fat (g)		<5
Calcium (mg)		<160
Phosphorus (mg)		<300
Potassium (mg)		<200
Sodium (mg)		≤140

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

4.6. FAT SUPPLEMENT: MCT

Description: Fat supplement containing >90% MCTs.

Indication for Use: For patients requiring an additional fat supplement as part of their diet.

Packaging

Item number:	RT9-04-007	In 50-100ml re-sealable container
Item number:	RT9-04-008	In 500 ml re-sealable container

Containing per 100ml:

Nutritional Composition	Minimum	Maximum
Energy (kJ)	3000	3800
Carbohydrate (g)	0	
Fat (g)	90	100
MCT (g)	80	100

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum
Energy (kJ)	3000	3800
Carbohydrate (g)	0	
Fat (g)	90	100
MCT (g)	80	100

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

4.7. L-GLUTAMINE SUPPLEMENT WITH ADDED ZINC, COPPER AND SELENIUM

Description: Pure L-glutamine with added zinc, copper and selenium, which can be administered to patients receiving oral nutrition or tube feeding.

Indication for Use: Indicated as a conditionally essential amino acid supplement in patients with increased metabolic stress and compromised gut integrity.

Packaging
Item number: RT9-04-009 In 10- 20 g sachets

Containing per sachet:

Nutritional Composition	Minimum	Maximum
Energy (kJ)		<300
Carbohydrate (g)		<8
Glutamine (g)	-	10
Zinc (mg)	3	4
Copper (mg)	0.4	0.6
Selenium (mcg)	18	28

The principal tests listed below must be performed to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum
Energy (kJ)		<300
Carbohydrate (g)		<8
Glutamine (g)		10
Zinc (mg)	3	4
Copper (mg)	0.4	0.6
Selenium (mcg)	18	28

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

5. CATEGORY FIVE: OTHER FEEDING PRODUCTS

5.1. NATURAL THICKENING POWDER FOR ADULTS

Description: A modified starch, instant food thickener in powder form that can thicken hot and cold fluids and all types of foods (from fluids to purees) without any cooking. It must thicken the liquid and retain the consistency of liquids or food when it stands for a period of time. The thickener must be fully digestible. It should be unflavoured and not affect the taste of the food it is added to. Not suitable for children below 3 years. The thickener must stop its action within one minute and must not bind fluids. Additives used and thickeners must adhere to codex general standards for food additives CXS 192-1995.

Indication for Use: To thicken foods and fluids for patients with swallowing abnormalities.

Packaging

Item number: RT9-05-001 In 5-20g sachets
Item number: RT9-05-002 In 100-150g resealable container (include a graded scoop as per reconstituted instructions)
Item number: RT9-05-003 In 200g - 300g resealable container (include a graded scoop as per reconstituted instructions)

Containing per 100g:

Nutritional Composition	Minimum	Maximum
Energy (kJ)		<1700
Protein (g)		<1.5
Carbohydrate (g)		<120
Fat (g)		<0.3
Potassium (mg)		<450
Sodium (mg)		<1500

The principal tests listed below must be performed in order to check if the quality of the product meets above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum
Energy (kJ)		<1700
Protein (g)		<1.5
Carbohydrate (g)		<120
Fat (g)		<0.3
Potassium (mg)		<450.0
Sodium (mg)		<1500

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

5.2. NATURAL THICKENING POWDER FOR INFANTS AND YOUNG CHILDREN

Description: An instant natural food thickener in powder form that can thicken liquids i.e., formula, milk, juice etc. It must thicken the liquid and retain the consistency of liquids or food when it stands for a period of time. The thickener must be fully digestible. It should be unflavoured and not affect the taste of the food it is added to. The thickener must stop its action within one minute and must not bind fluids. Additives and thickeners must adhere to the codex standards for infant formulas, formula for special medical purposes (CXS 72 -1981) and follow up formula (CXS 156-987), and the general standards for food additives (CXS 192-1995)

Indication for Use: For use in Infants and children.

Packaging

Item number: RT9-05-004 In 100g - 150g re-sealable container (include a graded scoop as per reconstituted instructions)

Item number: RT9-05-005 In 200g - 300g resealable container (include a graded scoop as per reconstituted instructions)

Containing per 100g:

Nutritional Composition	Minimum	Maximum
Energy (kJ)	1000	1800
Protein (g)		<3
Carbohydrate (g)		<100
Fat (g)		<1.5
Sodium (g)		<1.0

The principal tests listed below must be performed in order to check if the quality of the product meets above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum
Energy (kJ)	1000	1800
Protein (g)		<3
Carbohydrate (g)		<100
Fat (g)		<1.5
Sodium (g)		<1.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

5.3. SOLUBLE FIBRE SUPPLEMENT FOR CONSTIPATION

Description: A soluble fibre nutritional supplement. Lactose and Gluten free.

Indication for Use: For patients requiring additional fibre for the management of constipation.

Packaging

Item number: RT9-05-006 In 10- 30ml sachet

Containing per sachet:

Nutritional Composition	Minimum	Maximum
Carbohydrate (g)		<15.0
Fat (g)		0
Soluble Fibre (g)	8.0	12.0

The principal tests listed below must be performed in order to check if the quality of the product meets above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Minimum	Maximum
Carbohydrate (g)		<15.0
Fat (g)		0
Soluble Fibre (g)	8.0	12.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

5.4. SOLUBLE FIBRE SUPPLEMENT FOR MALABSORPTION

Description: A soluble fibre nutritional supplement. Lactose free and Gluten free.

Indication for Use: For patients requiring additional fibre for the management of increased gastrointestinal motility.

Packaging
Item number: RT9-05-007 In 10- 20g sachet

Containing per sachet:

Nutritional Composition	Minimum	Maximum
Carbohydrate (g)		<15.0
Fat (g)		0
Soluble Fibre (g)	1.5	3.0

The principal tests listed below must be performed in order to check if the quality of the product meets above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Containing per sachet:

Nutritional Composition	Minimum	Maximum
Carbohydrate (g)		<15.0
Fat (g)		0
Soluble Fibre (g)	1.5	3.0

Microbiological tests:

The methods to be employed for E. sakazakii (Cronobacter species) and Salmonella should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

or

Alternative analytical methods may be used when validated against the reference method using the protocols as set out in the ISO 16410 standard or any other similar internationally accepted protocols.

6. CATEGORY SIX: NUTRITION PRODUCTS FOR THE MANAGEMENT OF SEVERE ACUTE MALNUTRITION FOR CHILDREN 6 MONTHS-5 YEARS OF AGE

6.1. F-75 THERAPEUTIC FEED

Description: F-75 is a therapeutic feed with added vegetable fat, carbohydrates, vitamins and minerals intended for the stabilisation phase of treatment of children diagnosed with Severe Acute Malnutrition (SAM) with an energy density of 75 kcal/100ml. F-75 is a feed for special medical purposes which is administered under medical supervision. A cautious approach is required because of the child's fragile physiological state and reduced homeostatic capacity; hence, F-75 is not designed for weight gain.

Indication for Use: Children above the age of 6 months diagnosed with Severe Acute Malnutrition, in phase 1 of their treatment.

Packaging:

Item number:	RT9-06-001	In 100ml-150ml READY-TO-USE container (excluding re-tort pouches)
Item number:	RT9-06-002	In 200ml-250 ml READY-TO-USE container (excluding re-tort pouches)
Item number:	RT9-06-003	In 400ml-600ml READY-TO-USE container (excluding re-tort pouches)

Quality and Safety

General quality: milk-based white or pale yellowish liquid and should be free from impurities, coloured particles, caking and lumps.

Ingredients:

- milk powder
- refined vegetable oil
- Sugar
- Maltodextrin
- milk derivate
- emulsifier (e.g. lecithin)
- vitamins and mineral (optionally premix can be used).

F75 shall be free from objectionable matter. It shall not contain any toxic substances originating from microorganisms or any other poisonous or deleterious substances, including anti-nutritional factors, heavy metals or pesticide residues in amounts that may represent a hazard to health. It shall not contain detectable levels of residues of antibiotics or other veterinary drugs used in animal husbandry.

Formulation and Starting materials in F75 shall be manufactured referencing the formula described in the WHO document: Management of severe malnutrition: a manual for physicians and other senior health workers World health organization, 1999 (refer to Table 7, Table 8 and Appendix 4). http://www.who.int/nutrition/publications/severemalnutrition/9241545119/en/

The product must provide at least 50% of protein in the form of dairy protein. After reconstitution of powdered products according to the manufacturer´s preparation instruction and ready to use liquid products, the product shall be a homogenous liquid that does not separate into oil/liquid phases or leave a **solid sediment** upon standing. Frothing of the F75 powdered product after preparation should be minimal to enable accurate dosage measurements of the feed to each individual recipient. **The product should have a characteristic milk taste and smell. It shall be white as cream, shall not have rancid, pungent or unpleasant taste or smell.**

All ingredients, including optional ingredients, shall be clean, of good quality, safe and with minimal fibre removed when necessary. All ingredients and food additives shall be gluten free. Applicable local regulations and codex references for ingredients must be adhered to.

Milk: Full cream milk powder or Skimmed milk powder and/or Whey powder (NB: may produce bitter taste) may be used in the formulation of F-75. **The applicable standards reference are Codex Standard for Milk Powders and Cream Powder (CXS 207-1999) and Codex Standard for Whey Powders (CXS 289-1995).**

Carbohydrates: Carbohydrates used shall be gluten free and readily soluble in water. Lactose shall not be added. Glucose polymers can be used. **Applicable standards reference is Codex Standard for Sugars (CXS 212 – 1999).**

Oil: Edible refined vegetable oil. The manufacturer shall choose the type of oil and establish specifications for oil to ensure that the specifications in the finished product are met (with particular attention to requirements for omega 3 and omega 6 fatty acids). Hydrogenated vegetable oils are not to be used. Applicable standards reference: Codex Standard for Named Vegetable Oils (CXS 210 -1999).

Protein: F75 approved for the initial feeding or starting phase of treatment of children with severe acute malnutrition must provide at least 50% of protein in the form of dairy protein. For the purposes of conversion from unit weight to unit energy, protein and carbohydrate are assumed to contribute 4 kcal/g and lipids 9 kcal/g.

Additives and Flavours: The use of artificial flavourings is not permitted; only natural flavourings may be used. Natural flavourings are defined in Codex Guidelines on General Requirements for Natural Flavourings (CXG 29-1987). The use of artificial antioxidants is not permitted, only natural antioxidants such as ascorbyl palmitate or mixed tocopherols may be used.

Other additives: Essential L-amino acids, choline, taurine, carnitine, inositol, carotene and other semi-essential or biologically valuable nutrients may be added to meet the specification at levels considered safe for children with severe acute malnutrition.

Shelf life: The product shall retain the above-mentioned specifications for at least 18-24 months for powder and 9-12 months for liquids from date of manufacture when stored in dry conditions at a temperature of 30°C, supported by real time shelf life data. Shelf life studies shall be conducted in accordance with the Requirements for stability studies as per the WHO standards.

Microbiological criteria: Manufacturers are responsible for ensuring the compliance of finished products with the microbiological criteria as specified. In regard to limitations of the end-product testing the compliance shall be ensured through the design of an appropriate food safety control system and verification of the effectiveness of the applied control measures through appropriate auditing methods, including review of monitoring records, deviations and assuring that critical control points (CCPs) are kept under control and good hygienic practices (GHPs) are adhered to. These activities can be supplemented, as necessary, by appropriately documented microbiological sampling and analysis plans. The microbiological testing shall include, as appropriate, analysis of samples taken from starting materials, environment, production line and finished product. Environmental samples shall be taken from both: the points considered as most likely to cause product contamination and being most contaminated. **Where results of monitoring the control measures and surveillance or verification indicate that the product batch, lot or consignment, or its part is unsafe (not in compliance with the set microbiological criteria), it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.**

Processing requirements: All processing and drying shall be carried out in a manner that minimizes loss of nutritive value, particularly protein quality and vitamin content. Products must be manufactured in accordance with the Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children. (CXC 66 – 2008) and Recommended International Code of Practice. General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003), and other applicable codex references and GMPs (Good manufacturing practices).

Pesticides, Heavy Metals and Contaminants

Verifying that pesticide and heavy metals levels are below accepted limits is the responsibility of the manufacturer. Examples of mycotoxins, pesticides and heavy metals that must be controlled, include, but are not limited to:

- Nitrates < 200mg NO3/kg
- Nitrites < 2mg NO2/kg
- Aluminium < 0.6mg/kg
- Melamine < 1mg/kg

Mycotoxins (as per Codex standard when applicable for the starting materials used)

- Ochratoxin A <0.5ppb
- Aflatoxin B1 <0.1ppb
- Aflatoxin M1 <0.025ppb
- Palutin <10ppb
- Deoxynivalenol <200ppb
- Zearalenone <20ppb
- Fumonisins <200ppb

Applicable Codex standards references include: Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CXC 49-2001): General Methods of Analysis for Contaminants (CXS 228-2001); and Codex General Standard for Contaminants and Toxins in Food (CXS 193-1995).

Pesticides: Pesticide levels must be below 10 ppb. Verifying pesticide levels are below accepted limits is the responsibility of the manufacturer.

- Carbamates <10 ppb
- Organochlorines<10 ppb
- Organophosphates <10 ppb
- Pyrethroids <10 ppb

The maximum residue levels of specific pesticides or their metabolites in F75 set in below shall not exceed:

Substance and Maximum residue level (mg/kg)

- Cadusafos: 0.006 Demeton-S-methyl/demeton-S.methyl sulfone/ oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl) 0.006
- Ethoprophos 0.008
- Fipronil (sum of fipronil and fipronil-deslfinyl, expressed as finpronil) 0.004
- Propineb/propylenethiourea (sum of propined and propylenethiourea) 0.006

The following pesticides shall not be used in the agricultural production intended for the production of F75:

- Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone, expressed as disulfoton) Fensulfotion (sum o fensulfothion, its oxygen analogue and their sulfone, expressed as fensulfothion) Fentin, expressed as triphenyltin cation

- Haloxfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop) Hexachlorobenzene Nitrofen
- Ometholate
- Terbufos (sum of terbufos, ist sulfoxide and sulfone, expressed as terbufos)
- Aldrin and dieldrin, expressed as dieldrin, Endrin

Applicable Codex standards reference is Analysis of Pesticide Residues: Recommended Methods (CXS 229-1993, REV.1-2003)

Heavy metals*: Verifying that heavy metal levels are below accepted limits is the responsibility of the manufacturer. Examples of heavy metals that must be controlled include, but are not limited to:

- Arsenic <0.052mg/kg
- Cadmium <0.112mg/kg
- Lead <0.2mg/kg
- Mercury<0.037mg/kg
- Tin <105mg/kg

*Based on 5 kg child with SAM and PTWI, General Standard for Contaminants and Toxins in Food and feed (CXS 193- 1995).

- Hydrocarbons Benzo[a]pyrene <1ppb

Radioactivity: Radioactive contamination can occur when using milk powder derived from cows that have eaten contaminated feed. This risk is managed by using certified radioactivity free milk products. The nuclear radiation level shall meet the values valid in the area of consumption. If limits are not defined, the value must not exceed 370Bq/kg (Cs 134 & Cs136). The product and its components shall not be treated by ionizing radiation.

Nutritional Composition

Table 1: Nutritional Composition per 100ml

Nutrients and nutritional values per 100ml finished product	Unit	Minimum	Maximum
Energy	kcal	70	80
Protein	g	0.75	1.5
Fat	g	2.0	3.0
omega-3 fatty acids	0.3 – 2.5% total energy		
omega-6 fatty acids	3 – 10% total energy		
Ash	Maximum 4.0%		
Moisture	Maximum 4%		
Lactose	<1.4g		
Osmolarity	mmol/L	240	320
carbohydrates	g	10.5	14
Vitamin A	mg RE	0.1	0.3
Thiamin	mg	0.08	
Riboflavin	mg	0.3	
Niacin	mg	0.8	
Pantothenic Acid	mg	0.5	

Nutrients and nutritional values per 100ml finished product	Unit	Minimum	Maximum
Pyridoxine	mg	0.1	
Biotin	mcg	10	
Folic acid	mcg	35	
Vitamin B12	mcg	0.3	
Vitamin C	mg	10	
Vitamin D	mcg	2.5	5.0
Vitamin E	mg	3.3	6.5
Vitamin K	mcg	2.5	
Calcium	mg	50	100
Copper	mg	0.2	0.3
Iodine	mcg	12.3	24.5
Iron	mg		0.05
Magnesium	mg	8.5	11
Phosphorus	mg	50	100
Potassium	mg	122	156
Selenium	mcg	3.5	7
Sodium	mg		17
Zinc	mg	1.8	3.0

Vitamins and minerals

- The used nutrient compounds shall comply with the criteria established in Advisory lists of Nutrient Compounds for use in foods for Special Dietary uses for Infants and Young Children (CXG 10 – 1979 (Rev. 2008 last amendment 2015).
- Another list of acceptable vitamin compounds can be found in Annexure 3 of the COMMISSION DIRECTIVE 2006/141/EC of 22 December 2006 on infant formulae, follow-on formulae and amending Directive 1999/21/EC.
- If the manufacturer uses a mineral and vitamin premix(es), they must source it from a premix manufacturer/s who adhere to GMP standards.
- Vitamins and minerals shall be in such forms that they are easily absorbed by patients with SAM who are often achlorhydric. The added minerals shall be water-soluble and shall not form insoluble components when mixed together. **Iron salts are not to be added.**
- The F75 shall have a mineral composition that will not alter the acid-base metabolism of patients with SAM. In particular, it shall have a moderate positive non- metabolisable base sufficient to eliminate the risk of metabolic acidosis.
- The non-metabolisable base can be estimated using the formula: Estimated absorbed millimoles (sodium+potasium+calcium+magnesium) minus (phosphates + chlorides) See: http://www.who.int/maternal_child_adolescent/documents/a91065/en/
- Added minerals shall be in the form of water-soluble salts. Minerals used shall be in forms that are known to be bioavailable, nitrite and nitrate salts shall not be used. Recommended forms of minerals can be found in Appendix 4, Management of Severe Malnutrition a manual for senior health workers.
  http://www.who.int/nutrition/publications/severemalnutrition/9241545119/en/
  http://apps.who.int/iris/bitstream/10665/44295/1/9789280641479_eng.pdf?ua=1

Packaging

Primary packaging

All packaging material being in contact with food or intended to come in contact with food, including inks and glue shall be of food-contact grade. Product shall be packed in a suitable container (refer to special conditions of contract). Packaging under inert gas (nitrogen or carbon dioxide) prolongs products shelf-life and is recommended. Packaging must be free of damage such as, but not limited to tears, cuts, holes, and abrasions through one or more layers, leakage of any seal. The closure seal must be free of wrinkles and occluded maters.

Powdered product containers should be hermetically sealed and resistant to humid and hot climates. Seal and container integrity for F75 products shall be adequate to withstand pressure changes associated with international distribution channels such as air transport. The powdered container shall be capped with a reusable lid to adequately close the container and protect its content form external contamination and humidity during storage. The opened powdered container can be used within a minimum of 4 weeks.

The label shall contain the following information:

- Generic name: F-75 Therapeutic Feed
- Clear statement: For the initial phase (or Phase 1) of treatment of Children > 6 months with Severe Acute Malnutrition.
- Use under medical supervision.

Minimum requirement for release of F 75

The manufacturer must elaborate and implement an analytical plan of the finished product, starting materials and the processing environment. All analytical test procedures must be described in sufficient details, e.g. the sampling plan, acceptance/release criteria, analytical methods. SANAS accredited laboratories or ISO 17025 certified laboratories shall preferably be used.

Certificate of Analysis (CoA) may be required for every batch supplied to End-Users and shall be forwarded prior to its supply. The manufacturer is expected to perform the necessary finish product analysis in order to prove that the batch complies with the specification. In case vitamin and mineral premix is used it may be adequate to test for tracers. In case single addition of vitamins and minerals are used, then individual analysis of each component is expected.

The principal tests listed below must be performed in order to check if the quality of F-75 meets above requirements. The validated method of analysis for the used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

Table 2: List of Compulsory Tests per 100ml

Nutrients and nutritional values per 100ml finished product	Unit	Minimum	Maximum
Energy	kcal	70	80
Protein	g	0.75	1.5
Fat	g	2.0	3.0
Ash	Maximum 4.0%		
Moisture	Maximum 4%		
Lactose	<1.4g		
Osmolarity	mmol/L	240	320
Carbohydrates	g	10.5	14
Vitamin A	mg RE	0.1	0.3
Vitamin C	mg	10	
Vitamin D	mcg	2.5	5.0
Iron	mg		0.05
Potassium	mg	122	156
Sodium	mg		17

The manufacturer must conduct at least one complete finished product analysis annually in order to verify that the finished product is manufactured according to this specification.

6.2. F-100 THERAPEUTIC FEED

Description: F-100 is a therapeutic feed with added vegetable fat, carbohydrates, vitamins and minerals intended for the rehabilitation phase of treatment of children diagnosed with Severe Acute Malnutrition with an energy density of 100 kcal/100ml. F-100 is a food for special medical purposes, which is administered under medical supervision.

Indication for Use: Children aged 6 months and over diagnosed with Severe Acute Malnutrition, in phase 2, or nutritional rehabilitation phase of their treatment.

Packaging:

Item number: RT9-06-004 In 200-250ml READY-TO-USE container (excluding re-tort pouches)
Item number: RT9-06-005 In 400-600ml READY-TO-USE container (excluding re-tort pouches)

T**ECHNICAL SPECIFICATIO**NS

Quality and Safety

Milk-based white or pale yellowish liquid; free from impurities, coloured particles, caking or lumps.
Ingredients:

- milk powder
- refined vegetable oil
- Sugar

- Maltodextrin
- milk derivate
- emulsifier (e.g., lecithin)
- vitamin and mineral (optionally premix can be used).

All ingredients, including optional ingredients, shall be clean, of good quality, safe and with minimal fibre removed when necessary. All ingredients and food additives shall be gluten free. F-100 shall be free from objectionable matter. It shall not contain any toxic substances originating from microorganisms or any other poisonous or deleterious substances, including anti-nutritional factors, heavy metals or pesticide residues in amounts that may represent a hazard to health. It shall not contain detectable levels of residues of antibiotics or other veterinary drugs used in animal husbandry.

Formulation and Starre-sealable ting materials F100 shall be manufactured referencing the formula described in the WHO document: Management of severe malnutrition: a manual for physicians and other senior health workers World Health Organization, 1999 (refer to Table 7, Table 8 and Appendix 4). http://www.who.int/nutrition/publications/severemalnutrition/9241545119/en/
The product must provide at least 50% of protein in the form of dairy protein. After reconstitution of powdered products according to the manufacturer´s preparation instruction and ready to use liquid products, the product shall be a homogenous liquid that does not separate into oil/liquid phases or leave a **solid sediment** upon standing. Frothing of the F-100 powdered product after preparation should be minimal to enable accurate dosage measurements of the feed to each individual recipient. **The product should have a characteristic milk taste and smell. It shall be white or pale yellowish liquid, shall not have rancid, pungent or unpleasant taste or smell.**

All ingredients, including optional ingredients, shall be clean, of good quality, safe and with minimal fibre removed when necessary. All ingredients and food additives shall be gluten free. Applicable local regulations and codex references for ingredients must be adhered to.

Milk: Full cream milk powder or Skimmed milk powder and/or Whey powder (NB may produce bitter taste) may be used in the formulation of F-100. **The applicable standards reference are Codex Standard for Milk Powders and Cream Powder (CXS 207-1999) and Codex Standard for Whey Powders (CXS 289-1995).**

Carbohydrates: Carbohydrates used shall be gluten free and readily soluble in water. Glucose polymers and lactose may be used. **Applicable standards reference is Codex Standard for Sugars (CXS 212 – 1999).**

Oil: Edible refined vegetable oil. The manufacturer shall choose the type of oil and establish specifications for oil to ensure that the specifications in finished product are met (with particular attention to requirements for omega 3 and omega 6 fatty acids. Hydrogenated vegetable oils are not to be used. Applicable standards reference: Codex Standard for Named Vegetable Oils (CXS 210 -1999).

Protein: F-100 approved for the rehabilitation phase of treatment of children with severe acute malnutrition must provide at least 50% of protein in the form of dairy protein. For the purposes of conversion from unit weight to unit energy, protein and carbohydrate are assumed to contribute 4 kcal/g and lipids 9 kcal/g.

Additives and Flavours: The use of artificial flavourings is not permitted; only natural flavourings may be used. Natural flavourings are defined in Codex Guidelines on General Requirements for Natural Flavourings (CXG 29-1987). The use of artificial antioxidants is not permitted, only natural antioxidants such as ascorbyl palmitate or mixed tocopherols may be used.

Other additives: Essential L-amino acids, choline, taurine, carnitine, inositol, carotene and other semi-essential or biologically valuable nutrients may be added to meet the specification at levels considered safe for children with severe malnutrition.

Shelf life: The product shall retain the above-mentioned specifications for at least 18-24 months for powder and for the liquid 9-12 months from date of manufacture when stored in dry conditions at a temperature of 30°C, supported by real time shelf-life data. Shelf-life studies shall be conducted in accordance with the Requirements for stability study as per WHO standards.

Microbiological criteria: Manufacturers are responsible for ensuring the compliance of finished products with the microbiological criteria as specified. With regards to limitations of the end-product testing the compliance shall be ensured through the design of an appropriate food safety control system and verification of the effectiveness of the applied control measures through appropriate auditing methods, including review of monitoring records, deviations and assuring that critical control points (CCPs) are kept under control and good hygienic practices (GHPs) are adhered to. These activities can be supplemented, as necessary, by appropriately documented microbiological sampling and analysis plans. The microbiological testing shall include, as appropriate, analysis of samples taken from starting materials, environment, production line and finished product. Environmental samples shall be taken from both: the points considered as most likely to cause product contamination and being most contaminated. Where results of monitoring the control measures and surveillance or verification indicate that the product batch, lot or consignment, or its part is unsafe (not in compliance with the set microbiological criteria), it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

Processing requirements: All processing and drying shall be carried out in a manner that minimizes loss of nutritive value, particularly protein quality and vitamin content. Products must be manufactured in accordance with the Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children. (CXC 66 – 2008) and Recommended International Code of Practice. General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003), and other applicable codex references and GMPs (Good manufacturing practices).

Pesticides, Heavy Metals and Contaminants

Verifying that pesticide and heavy metals levels are below accepted limits is the responsibility of the manufacturer. Examples of mycotoxins, pesticides and heavy metals that must be controlled, include, but are not limited to:

- Nitrates < 200mg NO_3/kg
- Nitrites < 2mg NO_2/kg
- Aluminium < 0.6mg/kg
- Melamine < 1mg/kg

Mycotoxins (as per Codex standard when applicable for the starting materials used)

- Ochratoxin A <0.5ppb
- Aflatoxin B1 <0.1ppb
- Aflatoxin M1 <0.025ppb
- Palutin <10ppb
- Deoxynivalenol <200ppb
- Zearalenone <20ppb
- Fumonisins <200ppb

Applicable Codex standards reference include Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CXC 49-2001);: General Methods of Analysis for Contaminants (CXS 228-2001); and Codex General Standard for Contaminants and Toxins in Food (CXS 193-1995).

Pesticides: Pesticide levels must be below 10 ppb. Verifying pesticide levels are below accepted limits is the responsibility of the manufacturer.

- Carbamates <10 ppb
- Organochlorines<10 ppb
- Organophosphates <10 ppb
- Pyrethroids <10 ppb

The maximum residue levels of specific pesticides or their metabolites in F100 set in below shall not exceed:
Substance and Maximum residue level (mg/kg)

- Cadusafos: 0.006 Demeton-S-methyl/demeton-S.methyl sulfone/ oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl) 0.006
- Ethoprophos 0.008
- Fipronil (sum of fipronil and fipronil-deslfinyl, expressed as finpronil) 0.004
- Propineb/propylenethiourea (sum of propined and propylenethiourea) 0.006

The following pesticides shall not be used in the agricultural production intended for the production of F100:

- Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone, expressed as disulfoton) Fensulfotion (sum o fensulfothion, its oxygen analogue and their sulfone, expressed as fensulfothion) Fentin, expressed as triphenyltin cation
- Haloxfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop) Hexachlorobenzene Nitrofen
- Ometholate
- Terbufos (sum of terbufos, ist sulfoxide and sulfone, expressed as terbufos)
- Aldrin and dieldrin, expressed as dieldrin, Endrin

Applicable Codex standards reference is Analysis of Pesticide Residues: Recommended Methods (CXS 229-1993, REV.1-2003)

Heavy metals*: Verifying that heavy metal levels are below accepted limits is the responsibility of the manufacturer. Examples of heavy metals that must be controlled include, but are not limited to:

- Arsenic <0.052mg/kg
- Cadmium <0.112mg/kg
- Lead <0.2mg/kg
- Mercury<0.037mg/kg
- Tin <105mg/kg

*Based on 5 kg child with SAM and PTWI, General Standard for Contaminants and Toxins in Food and feed (CXS 193- 1995).

- Hydrocarbons Benzo[a]pyrene <1ppb

Radioactivity: Radioactive contamination can occur when using milk powder derived from cows that have eaten contaminated feed. This risk is managed by using certified radioactivity free milk products. The nuclear radiation level shall meet the values valid in the area of consumption. If limits are not defined, the value must not exceed 370Bq/kg (Cs 134 & Cs136). The product and its components shall not be treated by ionizing radiation.

Nutritional Composition

Table 1: Nutritional Composition per 100ml

Nutrients and nutritional values per 100ml finished product	Unit	Minimum	Maximum
Energy	kcal	95	105
Protein	g	2.3	3.1
Fat	g	4.9	6.9
Carbohydrates	g	7	12
omega-3 fatty acids	0.3 – 2.5% total energy		
omega-6 fatty acids	3 – 10% total energy		
Ash	Maximum 4.0%		
Moisture	Maximum 2.5%		
Lactose	G		4.4
Osmolarity	mmol/L	260	320
Vitamin A	mg RE	0.15	0.32
Thiamin	mg	0.1	
Riboflavin	mg	0.3	
Niacin	mg	1.0	
Pantothenic Acid	mg	0.6	
Pyridoxine	mg	0.1	
Biotin	mcg	11	
Folic acid	mcg	38	
Vitamin B12	mcg	0.3	
Vitamin C	mg	9.6	
Vitamin D	mcg	3.0	5.3
Vitamin E	mg	4.0	6.5
Vitamin K	mcg	3.0	
Calcium	mg	55	115
Copper	mg	0.25	0.35
Iodine	mcg	13	27
Iron	mg		0.05
Magnesium	mg	15	25
Phosphorus	mg	55	115
Potassium	mg	210	270
Selenium	mcg	3.5	7.7
Sodium	mg		55
Zinc	mg	2.0	3.0

Vitamins and minerals

- The used nutrient compounds shall comply with the criteria established in Advisory lists of Nutrient Compounds for use in foods for Special Dietary uses for Infants and Young Children (CXG 10 – 1979 (Rev. 2008 last amendment 2015).

- Another list of acceptable vitamin compounds can be found in Annex 3 of the COMMISSION DIRECTIVE 2006/141/EC of 22 December 2006 on infant formulae, follow-on formulae and amending Directive 1999/21/EC.
- If the manufacturer uses a mineral and vitamin premix(es), they must source it from an approved GMP manufacturer.
- Vitamins and minerals shall be in such forms that they are easily absorbed by patients with SAM who are often achlorhydric. The added minerals shall be water-soluble and shall not form insoluble components when mixed together. Iron salts are not to be added.
- F-100 shall have a mineral composition that will not alter the acid-base metabolism of patients with SAM. In particular, it shall have a moderate positive non- metabolisable base sufficient to eliminate the risk of metabolic acidosis.
- The non-metabolisable base can be estimated using the formula: Estimated absorbed millimoles (sodium+potasium+calcium+magnesium) minus (phosphates + chlorides) See: http://www.who.int/maternal_child_adolescent/documents/a91065/en/
- Added minerals shall be in the form of water soluble salts. Minerals used shall be in forms that are known to be bioavailable, nitrite and nitrate salts shall not be used. Recommended forms of minerals can be found in Appendix 4, Management of Severe Malnutrition a manual for senior health workers.
  http://www.who.int/nutrition/publications/severemalnutrition/9241545119/en/
  http://apps.who.int/iris/bitstream/10665/44295/1/9789280641479_eng.pdf?ua=1

Packaging

Primary packaging

All packaging material being in contact with food or intended to come in contact with food, including inks and glue shall be of food-contact grade. Product shall be packed in a suitable container (refer to special conditions of contract). Packaging under inert gas (nitrogen or carbon dioxide) prolongs products shelf-life and is recommended. Packaging must be free of damage such as, but not limited to tears, cuts, holes, and abrasions through one or more layers, and leakage of any seal. The closure seal must be free of wrinkles and occluded maters.

Powdered product containers should be hermetically sealed and resistant to humid and hot climates. Seal and container integrity for F100 products shall be adequate to withstand pressure changes associated with international distribution channels such as air transport. The powdered container shall be capped with a reusable lid to adequately close the container and protect its contents from external contamination and humidity during storage. The opened powdered container can be used within a minimum of 4 weeks.

The label shall contain the following information:

- Generic name: F-100 Therapeutic Feed
- Clear statement: A Food for Special Medical Purposes for the dietary management of Children > 6 months with Severe Acute Malnutrition [For the rehabilitation phase (phase 2)].
- Use under medical supervision.

Minimum requirement for release of F-100

The manufacturer must elaborate and implement an analytical plan of the finished product, starting materials and the processing environment. All analytical test procedures must be described in sufficient details, e.g., the sampling plan, acceptance/release criteria, analytical methods. SANAS accredited laboratories or ISO 17025 certified laboratories shall preferably be used.

Certificate of Analysis (CoA) may be required for every batch supplied to End-Users and shall be forwarded prior to its shipment. The manufacturer is expected to perform the necessary finish product analysis in order to prove that the batch complies with the specification. In case vitamin and mineral

premix is used it may be adequate to test for tracers. In case single addition of vitamins and minerals are used, then individual analysis of each component is expected.

The principal tests listed below must be performed in order to check if the quality of F-100 meets above requirements. The validated method of analysis for the used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

Table 2: List of Compulsory Tests

Nutrients and nutritional values per 100ml finished product	Unit	Minimum	Maximum
Energy	kcal	95	105
Protein	G	2.3	3.1
Fat	G	4.9	6.9
Carbohydrates	G	7	12
Ash	Maximum 4.0%		
Moisture	Maximum 2.5%		
Osmolarity	mmol/L	260	320
Vitamin A	mg RE	0.15	0.32
Vitamin C	Mg	9.6	
Iron	Mg		0.05
Potassium	Mg	210	270
Sodium	mg		55

The manufacturer must conduct at least one complete finished product analysis annually in order to verify that the finished product is manufactured according to this specification.

6.3. READY TO USE THERAPEUTIC FOOD FOR CHILDREN WITH SEVERE ACUTE MALNUTRITION

Description*:* **Ready-to-Use Therapeutic Foods (RUTF)** paste is a food for special medical purposes and is high-energy and contains adequate protein and other essential nutrients for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications and with appetite. These foods should be soft or crushable and should be easy for children to eat without any prior preparation.

Indication for Use

RUTF paste is the sole source of nutrition, except for breast milk in the case of breast-fed infants, during the period of SAM treatment for children aged 6 to 59 months with severe wasting without medical complications and with appetite. RUTF paste is ready to eat, directly from the sachet without prior cooking, mixing or dilution. RUTF paste is portion controlled: each unit has the same nutritional value for control and monitoring of dietary intake.

Packaging
Item number: RT9-06-006 In 90g- 100g sachet

TECHNICAL SPECIFICATIONS

a. Quality and Safety

RUTF shall be manufactured from ingredients that are fresh, of good quality, free from foreign materials and substances hazardous to health, that comply with the applicable regulations or Codex Alimentarius standards.

Texture: Smooth, homogeneous, thick paste, easy to squeeze out of sachet. It should be a uniform paste with no lumps or grittiness, having a small particle size (size < 200 microns) to minimise phase separation, granularity, and oil leaking out of the sachet. The paste should not elicit chewing when consumed by target population.

- ***Flavour and odour:*** RUTF paste should have a pleasing sweet, fresh flavour. RUTF paste should be free from foreign odours and flavours such as, (but not limited to) burnt, scorched, rancid, malted, sour, or stale. Artificial flavourings are not allowed. Only natural flavours are allowed.
- ***Colour:*** RUTF paste should have cream to light or orangey brown colour. The RUTF paste should not have a dull, grey re-sealable tinge, or other abnormal cast. It should show no evidence of excessive hearting (materially darkened or scorched).
- RUTF shall be free from objectionable matter; free from micro-organisms in amounts which may represent a hazard to health; not contain any substances originating from micro-organisms or any other poisonous or deleterious substances such as residues of hormones, antibiotics, pharmacologically active substances, anti-nutritional factors, heavy metals or pesticides residues, in amounts which may represent a hazard to health of children 6 months and older with severe acute malnutrition.
- RUTF is a low-moisture food with a water activity of 0.6 or below. Applicable Codex reference include: *Codex of Hygienic Practice for Low moisture foods (*CXC 75 2012, (2016) and Recommended *International Code of Practice. General Principles of Food Hygiene (CXC 1-1969, Rev. 4-2003).*

- **Milk and dairy ingredients** such as milk powder, whey powder or dairy permeate powder can be included in RUTF, and the Applicable standards reference are: *Codex Standard for Milk Powders and Cream Powder* (CXS 207-1999); *Codex Standard for Whey Powders* (CXS 289- 995); *Codex Standard for Edible Casein Products* (CXS 290-1995); and *Standard for Dairy Permeate Powders* (CXS 331-2017).
- **Peanuts and peanut paste**: ground peanuts must meet the following standards and their revisions: *Codex Standard for Peanuts* (CXS 200-1995) *and Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts or Appropriate codex standards for alternative ingredients to peanuts* (CAC/RCP 55-2004).
- **Oil (edible refined vegetable oil):** The manufacturer should choose judiciously the type of oil and establish specifications for oil to ensure that finished product specifications are met (with particular attention to requirements for omega-3 and omega- 6), providing essential fatty acids. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour, and shelf life. Partially hydrogenated fats and oils should not be used in RUTF. Trans fats must be kept to a minimum. Oil ingredients must comply with the most recent version of the relevant codex standards.

  <u>Applicable Codex Alimentarius standards reference:</u>

1. CXS 210-1999 (updated 2019) Codex Standard for Named Vegetable Oils Code of Practice for the reduction of 3-Monochloroprane-1-2- DIOL Esters (3-MCPDEs) and GLYCYCIDL Esters (GEs) in Refined Oils and Food Products made with refined oils.
2. Trans-fat: CXS 72-1981 Standard for Infant Formula and Formulas for Special Medical Purposes intended for Infants rev 2007

- **Carbohydrates:** Carbohydrates are used to achieve energy requirements in balance with proteins and lipids. Lactose, plant starch, maltodextrin and sucrose are the preferred carbohydrates in RUTF. Only precooked and/or gelatinized starches may be added. Free sugars should be limited and should not exceed 20% of total energy. Glucose and fructose should not be used. Carbohydrates must adhere to the relevant Codex Alimentarius texts. Honey must not be used in RUTF due to the risk of infant botulism from Clostridium botulinum. Attention should be given to the sugar (sucrose) particle size, which if not properly ground, could cause oil separation from the paste and lead to oil leakage when opening the sealed part of the sachet. **The reference standard is *Codex Standard for Sugars* (CXS 212-1999).**

- **Proteins:** Protein quality shall be determined using Protein Digestibility Corrected Amino Acid Score (PDCAAS), calculated according to the reference amino acid requirement and scoring patterns related to catch up growth of 10 g/kg/day in the target population for RUTF which is children with SAM aged 6 to 59 months.
    - **The PDCAAS for RUTF paste shall not be less than 90.**
    - The PDCAAS shall be calculated using, appropriate digestibility values and the reference amino acid pattern as stipulated in the ***Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods (2018).***
    - High quality protein will be achieved with RUTF formulations containing a minimum of 50% of protein from milk products.
    - In formulations with lower PDCAAS scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The addition of limiting amino acids, solely in the L-form, shall be permitted only in amounts necessary to improve the protein quality of the RUTF
- **Food Additives:** Only the food additives listed in Table 1 below ***(Table 1: Food Additives in RUTF Formulation)*** or in the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979) may be present in the RUTF paste. Other than by direct addition, an additive may be present in RUTF as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:
    - The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to the *General Standard for Food Additives* (CXS 192-1995)
    - The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in the *General Standard for Food Additives* (CXS 192-1995); and
    - The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of the raw materials or ingredients under proper technological conditions or good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the *General Standard for Food Additives* (CXS 192-1995).

Table 1: Food Additives in RUTF paste Formulation

Functional Class	Food Additive	International Numbering System (INS)	Maximum Use Level
Emulsifier	Mono- and di-glycerides of fatty acids	471	4 000 mg/kg
	Citric and fatty acid esters of glycerol	472c	9 000 mg/kg
	Lecithin	322(i)	5 000 mg/kg
Antioxidant	Ascorbyl palmitate	304	10 mg/kg
	Tocopherol concentrate, mixed	307b	10 mg/kg
	Ascorbic acid, L-	300	GMP
Acidity Regulator	Citric acid	330	GMP
Packaging Gas	Nitrogen	941	GMP
	Carbon dioxide	290	GMP
Carrier	Silicon dioxide, amorphous	551	10 mg/kg

b. **Shelf life*:*** The shelf life of RUTF shall be 24 months when stored at <30 degrees Celsius. Shelf-life claims should be supported by stability studies, please refer to the *Requirements for Stability Studies* in the special conditions of the contract. RUTF products should be of fresh production having at least 80% of their shelf life.

c. **Microbiological tests**: The manufacturer is responsible to elaborate an analytical plan for the RUTF paste finished product. All analytical test procedures must be described in sufficient detail, including analysis methods. ISO 17025 certified laboratories should preferably be used. Analytical control plans should be detailed and include tests for *Salmonella* & Enterobacteriaceae. Following the sampling plan and recommended method (or alternative validated method) as detailed in Appendix 1 of the *Codex of Hygienic Practice for Low moisture foods (*CXC 75 2012, (2016)) for Salmonella: Method: AOAC 975.55; AOAC 2003.01; ISO 21528-2, or alternative validated method. Applicable Codex Alimentarius standards reference:

1.CAC/GL 21, 1997. The Principles for the Establishment and Application of Microbiological Criteria for Foods (revision scheduled for 2013).
2.CAC/GL 63-2007: Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM).

d. **Pesticides, Heavy metals and other Contaminants:** Verifying that pesticide and heavy metals levels are below accepted limits is the responsibility of the manufacturer. Examples of mycotoxins, pesticides and heavy metals that must be controlled, include, but are not limited to:

- Mycotoxins: Aflatoxin: 10µg/ kg max
- Heavy metals: Arsenic, Cadmium, Lead, Mercury
- Pesticides: Carbamates Organochlorine Organophosphorous, pyrethroid
- The level of melamine must not exceed 1 mg/kg in milk products.
- RUTF paste and the ingredients used in such products comply with:

1.CXS 193-1995 General Standard for Contaminants and Toxins in Food and Feed 1995 (2015)

2.CXC 55-2004: Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts CXS 228 -2001 General Methods of Analysis for Contaminants.
3.CXC 49-2001 Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals.
4.CXM 2 Maximum residue limits (MRLs) and risk management recommendations (RMRr) for residues of veterinary drugs in foods Codex CX/MRL 2-2018, CX/MRL 2-2021.

e. **Processing Technologies:** Processing technologies used for RUTF and their ingredients shall be validated to prove that they do not alter the nutritional value of RUTF and that they allow the reduction of anti-nutritive factors. Milling or grinding, roasting, toasting are examples of processing technologies that can be used on ingredients.

Any technologies used should take into consideration the target group and any impact on the integrity of the nutrient content of the products. In addition to the practices described above, Good Hygiene Practices should be implemented for manufacturing of RUTF, according to the *General Principles of Food Hygiene* (CXC 1-1969) and *Code of Hygienic Practices for Low Moisture Foods* (CXC 75-2015) to avoid cross contamination during the storage of raw materials and the manufacturing process.
RUTF and/or their raw materials should be treated with a validated microbial reduction treatment in order to inactivate pathogens such as *Salmonella*, noting that some pathogens have increased heat resistance characteristics at reduced water activities in food matrices. Commonly used microbial reduction treatments that could be applied to RUTF and/or their raw materials include both thermal and non-thermal control measures.

For additional information on validation of control measures, refer to the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008). Additionally, refer to the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (MRM) (CXG 63-2007).

f. Vitamins and Minerals Premix

Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM. RUTF should have a mineral composition that leads to a moderate excess of non-metabolizable buffer base. The non-metabolizable buffer base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride).
All added vitamins and minerals must be in accordance with examples of mineral forms for RUTF formulation can be found in the WHO Management of severe malnutrition: A manual for physicians and other senior health workers (1999). The quantity of vitamins and minerals added to achieve the target level must be adjusted based on the chemical form, interaction, and impaired absorption with other nutrients and non-nutrients and scientific evidence showing adequate stability and bioavailability in the finished product. The mineral and vitamin premix(es) must be supplied from suitably qualified premix facilities. RUTF suppliers must validate their premix supplier to ensure the quality of the premix facility.

g. Nutritional Composition

The nutritional composition of RUTF is given in Table 2 including the upper and lower limits of each component. The value for each nutrient should be expressed in g, mg or mcg per 100 g of product.

Table 2: Nutritional Composition per 100g of RUTF paste

Nutrients and nutritional values per 100g finished product	Unit	Minimum	Maximum
Energy	kcal kJ	520 2176	550 2301
Protein	g	13	17
Fat	g	26	37
omega-3 fatty acids (1.0 – 2.5% total energy)	mg	580	1530
omega-6 fatty acids (3 – 7% total energy)	g	1.7	4.3
Trans-fatty acids	<3% total fat (1.1g/100g)		
Fibre	<5%		
Moisture Content	<2.5%		
Vitamin A	mg RE	0.8	1.6
Thiamin	mg	0.5	
Riboflavin	mg	1.6	
Niacin	mg	5	
Pantothenic Acid	mg	3	
Pyridoxine	mg	0.6	
Biotin	mcg	60	
Folic acid	mcg	200	
Vitamin B12	mcg	1.6	
Vitamin C	mg	50	
Vitamin D	mcg	15	22
Vitamin E	mg	20	
Vitamin K	mcg	15	30
Calcium	mg	300	785
Copper	mg	1.4	1.8
Iodine	mcg	70	140
Iron	mg	10	14
Magnesium	mg	80	235
Phosphorus	mg	300	785
Potassium	mg	1100	1600
Selenium	mcg	20	40
Sodium	mg	290	
Zinc	mg	11	14

***Expressed in terms of non-phytate Phosphorus**

h. Analytical requirements

The manufacturer should conduct a complete analysis of the finished product in order to verify that the finished product is manufactured in a homogeneous and consistent content. Analytical Certificate of Analysis (CoA) Requirements per Batch may be requested at any point in time during the contract and may also be required prior to each shipment or order collection for each batch provided.

List of Compulsory Tests

Nutrients and nutritional values per 100g finished product	Unit	Minimum	Maximum
Energy	kcal kJ	520 2176	550 2301
Protein	g	13	17
Fat	g	26	37
omega-3 fatty acids (1.0 – 2.5% total energy)	mg	580	1530
omega-6 fatty acids (3 – 7% total energy)	g	1.7	4.3
Trans-fatty acids	<3% total fat (1.1g/100g)		
Fibre	<5%		
Moisture Content	<2.5%		
Vitamin A	mg RE	0.8	1.6
Thiamin	mg	0.5	
Riboflavin	mg	1.6	
Niacin	mg	5	
Pantothenic Acid	mg	3	
Pyridoxine	mg	0.6	
Biore-sealable tin	mcg	60	
Folic acid	mcg	200	
Vitamin B12	mcg	1.6	
Vitamin C	mg	50	
Vitamin D	mcg	15	22
Vitamin E	mg	20	
Vitamin K	mcg	15	30
Calcium	mg	300	785
Copper	mg	1.4	1.8
Iodine	mcg	70	140
Iron	mg	10	14
Magnesium	mg	80	235
Phosphorus*	mg	300	785
Potassium	mg	1100	1600

Nutrients and nutritional values per 100g finished product	Unit	Minimum	Maximum
Selenium	mcg	20	40
Sodium	mg	290	
Zinc	mg	11	14

If a CoA is required it must mention the laboratory name, methods of analysis, laboratory variability ranges for each nutrient, specifications and targets for all the criteria below, to be applied to the finished product after primary packaging or anytime thereafter up to the point when the primary packaging is opened. It is recommended that methods of analysis and sampling of RUTF be in accordance with the Recommended Methods of Analysis and Sampling (CXS 234-1999).

Microbiological and Chemical criteria:

Microorganisms	N	c	M	M	p-class
Salmonella	25	0	Absent in 25 g	n/a	2
Enterobacteriaceae	10	2	<10 cfu/g	<100 cfu/g	3

Where

- n: number of sample units
- c: the maximum allowable number of defective sample units in a 2-class plan or marginally acceptable sample units in a 3-class plan
- m: a microbiological limit which, in a 2-class plan, separates good quality from defective quality or, in a 3-class plan, separates good quality from marginally acceptable quality
- M: a microbiological limit which, in a 3-class plan, separates marginally acceptable quality from defective quality
- P: 2 or 3 class plan

Salmonella: 0cfu per 25g Enterobacteriaceae
(EB): 10CFU PER G MAX TOTAL AFLATOXIN: 10 µg per Kg MAX (Provide laboratory analyses)
(see sampling plan and method references listed under '16.1 Microbiological Tests' section above.)
Applicable Reference: Code of Hygienic Practice for Low Moisture Content Foods CXC 75-2012 (updated 2016)

i. Packaging

Primary packaging

The primary packaging must be portion controlled: each unit of 92 g (maximum 100g) net. Packaging material cannot contain any detachable parts that present a choking hazard. Inks used for marking and glue must be contact food grade, water and lipid resistant. The pouch material must not transfer any element (particle, flavour or odour) to the product. Packaging material must ensure to withstand pressure changes associated with air transport. Pouches must be free of damage, such as (but not limited to) tears, cuts, holes, abrasions through one or more layers in the pouch material, leakage through any seal, etc. The primary packaging materials must not transfer particle, flavour or odour to the product. The closure seal must be free of wrinkles, occluded matter, or evidence of entrapped moisture or grease. An air and water tightness control must be implemented during the filling process. Packaging under nitrogen contributes to lengthen product shelf life, i.e. protecting lipid oxidation and vitamins from oxidising.

Applicable standard:
ASTM D 3985 (38°C and 50% RH): Oxygen transmission rate (O2TR) 0.06 cc/m2/24 hrs/atm
ASTM F 372 at 38°C and 90% RH): water vapor transmission rate 0.01 m/m2/24hrs
Secondary packaging
Cartons should be strong and sturdy, allowing stacking up to 2.4m high, resistant to puncturing and provide protection of the goods for carriage by road to end-users, including remote locations under adverse climatic and storage conditions and high humidity.
Cartons should be stacked on pallets and secured in the transportation vessel in a way that prevents movement during transportation. Pallets should be wrapped with plastic wrap to protect goods from contamination and movement of cartons during shipment.
Cartons should be protected by isolating sachets inside the carton in a plastic bag to prevent damaging other cartons in case of possible leakage.
It is recommended that RUTF be packaged in such a way to safeguard the hygienic and other qualities including nutritional properties of the food for the duration of its defined shelf-life.
The packaging materials shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission or local regulations have established a standard for any such substance used as packaging materials, that standard shall apply.

j. Labelling
Labelling of RUTF shall be in accordance with the applicable labelling regulations, *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-991), the *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (CXS 146-1985), and *Guidelines on Nutrition Labelling* (CXG 2- 1985).

- ***The label shall contain the following information:*** Generic name: Ready-to-Use Therapeutic Food (RUTF) paste
- Clear statement: A Food for Special Medical Purposes for the dietary management of Children from 6 to 59 months with Severe Acute Malnutrition [without medical complications].
- Use under medical supervision.

The following additional statements shall appear on the label of RUTF:
- The product is not to be used for nasogastric tube (NG tube) administration.
- The product should be used in conjunction with breastfeeding.
- Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for up to 2 years and beyond.

Instructions for Use:

- The label should indicate clearly from which age the product is recommended for use. The age shall not be less than 6 months for any product.
- The time within which the product should be consumed after opening should be clearly indicated.

6.4. READY-TO-USE LIPID-BASED NUTRIENT SUPPLEMENT- SMALL QUANTITY (LNS-SQ) PASTE PRODUCT FOR OLDER INFANTS AND YOUNG CHILDREN 6 TO 23 MONTHS, TO PREVENT UNDERNUTRITION.

Description:

Ready-to-Use Lipid-based Nutrient Supplement-small quantity (LNS-SQ) paste is a nutritionally fortified food used to complement the diet of infants and young children with essential nutrients. LNS-SQ is formulated to meet the nutritional needs of and prevent undernutrition, and to improve health, growth and development in older infants and young children aged 6 to 23 months. This product cannot be used as a replacement of breast milk.

Indication for Use: The product is intended to be used as a ready-to-use nutritional supplement to provide additional energy and essential nutrients to the diets of older infants and young children aged 6 to 23 months who are at risk of wasting or experiencing other forms of malnutrition, including stunting and micronutrient deficiencies, as part of a diversified diet.

Packaging

Item number: RT9-06-006 In 20g sachets

TECHNICAL SPECIFICATIONS

Texture

Smooth, homogeneous, thick paste, easy to squeeze out of the sachet. It should be a uniform paste with no lumps or grittiness, having a small particle size (e.g., < 500 microns). The paste should not elicit chewing when consumed by the target population. Attention should be given to the sugar (sucrose) and minerals particle size, which, if not properly ground, could contribute to oil separation from the paste and lead to oil leakage when opening the sealed part of the sachet.

Flavour and odour

LNS-SQ paste should have a pleasing sweet and fresh flavour. It should be free from foreign odours and flavours such as, (but not limited to) burnt, scorched, rancid, malted, sour, or stale.

Colour

LNS-SQ should have cream to light or orangey brown colour. It should not have a dull, grey tinge, or other abnormal cast. It should show no evidence of excessive heating (materially darkened or scorched).

Table 1: Nutritional Composition per 100g

Nutrients	Nutrients and nutritional values per 100g finished product	
	Min	Max
Energy value	Kcal 550 kJ 2301	Kcal 620 kJ 2595
Protein (g)	12	16
Lipids (g)	40	53
Added Sugar (g)		8
Omega-3 fatty acids (g)	2.5	4
Omega -6 fatty acids (g)	4	15
PDCAAS**	70	100
Vitamin A (mcg RE)	2000	3390
Vitamin C (mg)	75	169
Vitamin B1 (mg)	1.5	3.8
Vitamin B2 (mg)	2	3
Vitamin B6 (mg)	1.5	2.3
Vitamin B12 (mcg)	2.5	4.2
Biotin (mcg)	45	65
Folic Acid (mcg DFE)	667	1044
Pantothenic Acid (mg)	9	14
Niacin (mg)	20	28.8
Vitamin D3 (mcg)	25	52
Vitamin K (mcg)	150	323
Vitamin E (mg α-TE)	20	47
Calcium (mg)	1400	1960
Phosphorus (mg)	982	1375
Potassium (mg)	1000	1400
Magnesium (mg)	200	280
Zinc (mg)	40	56
Copper (mg)	1.7	2.2
Iron (mg)	30	42
Iodine (mcg)	450	742
Selenium (mcg)	100	160
Manganese (mg)	6	9
Sodium (mg)		270
Moisture Content		2.5%
Water Activity		0.6

**Preferable source of protein: dry skimmed milk protein 8-13 g/100 g (1.6-2.6 g/20g)*

***PDCAAS should not be less than 70 per cent of that of the WHO amino acid reference pattern for children from 2 – 5 years, where PDCAAS (%) = 100 X (mg of limiting amino acid in 1 g test protein)/ (mg*

of same amino acid in reference pattern) X true faecal digestibility of test protein (Reference: CA2487EN.pdf (fao.org) p. 17)

ANALYTICAL REQUIREMENTS

The principal tests listed below must be performed in order to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the right to request additional analyses in case of further quality assessment.

Table 2: List of Compulsory Tests

Nutrients	Nutritional values/ 100 g	
	Min	Max
Energy value	Kcal 550 kJ 2301	Kcal 620 kJ 2595
Protein (g)	12	16
Lipids (g)	40	53
Added Sugar (g)	-	8
Omega-3 fatty acids (g)	2.5	4
Omega -6 fatty acids (g)	4	15
PDCAAS**	70	100
Vitamin A (mcg RE)	2000	3390
Vitamin C (mg)	75	169
Vitamin B1 (mg)	1.5	3.8
Vitamin B2 (mg)	2	3
Vitamin B6 (mg)	1.5	2.3
Vitamin B12 (mcg)	2.5	4.2
Biotin (mcg)	45	65
Folic Acid (mcg DFE)	667	1044
Pantothenic Acid (mg)	9	14
Niacin (mg)	20	28.8
Vitamin D3 (mcg)	25	52
Vitamin K (mcg)	150	323
Vitamin E (mg α-TE)	20	47
Calcium (mg)	1400	1960
Phosphorus (mg)	982	1375
Potassium (mg)	1000	1400
Magnesium (mg)	200	280
Zinc (mg)	40	56
Copper (mg)	1.7	2.2
Iron (mg)	30	42
Iodine (mcg)	450	742
Selenium (mcg)	100	160
Manganese (mg)	6	9
Sodium (mg)		270

Nutrients	Nutritional values/ 100 g	
	Min	Max
Moisture Content		2.5%
Water Activity		0.6

Shelf life

24 months. Shelf-life claims should be supported by stability studies. Products should be of fresh production having at least 80% of their shelf life. The nutritional composition of LNS-SQ must remain within the minimum and maximum limits as mentioned in table 1 and table 2. There shall be no oil separation throughout the shelf life of the product.

Raw materials and Ingredients

LNS-SQ shall be manufactured from ingredients that are fresh, of good quality, free from foreign material and substances hazardous to health, that comply with Codex Alimentarius and relevant regulations. The quality of raw materials should be adequate so that the final product will meet all requirements specified in this specification.

Milk and dairy ingredients

Milk and dairy ingredients such as milk powder, whey powder or dairy permeate powder can be included in LNS-SQ.

Peanuts

Peanuts and peanut paste. Ingredients must comply with the latest version of the relevant codex standards.

Legumes

Soy based ingredients, chickpeas, lentils, and other legume products (e.g., flour and isolates) must comply with the latest version of the relevant codex standards.

Oil *(edible refined vegetable oil)*

The manufacturer should choose judiciously the type of oil and establish specifications for oil to ensure that finished product specifications are met (with particular attention to requirements for omega 3 and omega 6), providing essential fatty acids. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour, and shelf life. Partially hydrogenated fats and oils should not be used. Trans fats must be kept to a minimum. Oil ingredients must comply with the most recent version of the relevant codex standards.

Carbohydrates

Carbohydrates are used to provide energy and can be used to increase palatability of the LNS-SQ. Lactose, plant starch, maltodextrin and sucrose are the preferred carbohydrates in LNS-SQ. Only precooked and/or gelatinized starches may be added. Carbohydrates must adhere to the relevant Codex Alimentarius texts. Glucose and corn syrup products as ingredients and fructose ingredients should be avoided in LNS-SQ, because of potential adverse effects. Free sugars added for sweetness should be used sparingly, not more than 10% of energy.

Attention should be given to the sugar (sucrose) particle size, which if not properly ground, could cause oil separation from the paste and lead to oil leakage when opening the sealed part of the sachet. Starch and sugar ingredients must comply with the relevant codex standards.

Food additives

Only natural flavours are allowed. The following antioxidants may be included: Ascorbyl palmitate and Mixed tocopherols.

Not permitted as an antioxidant: Butylhydroxyanisol (BHA) and Butylated hydroxytoluene (BHT)

Mineral and vitamin premix

The mineral and vitamin premix(es) cannot be produced by the LNS-SQ paste manufacturer itself and must be supplied only from suitably qualified premix facilities.

Vitamin and mineral forms used must be soluble and easily absorbed by children with nutrients deficiency. The added minerals should be water-soluble and should not form insoluble components when mixed. The LNS-SQ paste should have a mineral composition complying with the nutritional premix composition listed in Table 3*. This premix is a guide to manufacturers only, and it will require adaption to your process and facility. Inclusion of the premix example below is at the manufacturer's own discretion, as compliance to the composition of LNS-SQ at the end of shelf life is the responsibility of the supplier.

Table 3. Example of Premix Contribution and Premix Nutrient Sources

Micronutrients	Unit	Recommended Nutrient Sources (*1) (/alternative options)	Nutrients addition (**2)/ 100 g LNS-SQ (+/-10%)
Retinol (Vit A)	mcg RE	Dry Vitamin A Palmitate/ Dry Vitamin A Acetate (***3)	2927
Thiamine (Vit B1)	mg	Thiamine hydrochloride/Thiamine mononitrate	3.4
Riboflavin (Vit B2)	mg	Riboflavin	2.7
Niacin (Vit B3)	mg	Niacinamide	26
Pantothenic acid (Vit B5)	mg	Calcium d-Pantothenate	12
Pyridoxine	mg	Pyridoxine hydrochloride	2
Biotin (Vit B7)	mcg	Biotin	56
Folic acid	mcg	Folic acid food grade	939
Cobalamin (Vit B12)	mcg DFE	Cyanocobalamin	3.7
Ascorbate (Vit C)	mg	Calcium ascorbate dihydrate; Ascorbic Acid fine powder	152
Cholecalciferol (Vit D)	mcg	Cholecalciferol	45
Vitamin E	mg α-TE	Vitamin E acetate (50% dl-alpha-tocopherol acetate)	28
Phytomenadione (Vit K)	mcg	Phytomenadione	203
Calcium (Ca)	mg	98.5% Ca from tricalcium phosphate and 1.4% Ca from Calcium ascorbate and 0.1% Ca from d-calcium pantothenate	1251
Copper (Cu)	mg	Copper sulfate anhydrous/Copper gluconate	1.8
Iodine (I)	mcg	Potassium Iodide	539
Iron (Fe)	mg	60% Fe from ferrous sulfate monohydrate and 40% Fe from NaFeEDTA 34	34

Micronutrients	Unit	Recommended Nutrient Sources (*1) (/alternative options)	Nutrients addition (**2)/ 100 g LNS-SQ (+/-10%)
Magnesium (Mg)	mg	Magnesium sulphate monohydrate/ magnesium citrate or gluconate	162
Manganese (Mn)	mg	Manganese sulfate monohydrate	6.5
Phosphorus (P)	mg	81% from tricalcium phosphate and 19% from dipotassium phosphate	785
Potassium (K	mg	61% from Dipotassium phosphate and 39% potassium chloride	612
Selenium (Se)	mcg	Sodium selenite/Sodium selenate	119
Zinc (Zn) mg Zinc sulfate monohydrate 44	mg	Zinc sulfate monohydrate	44

Emulsifying agents

Emulsifiers are potentially of importance for lipid-based pastes as this type of food is prone to phase separation. Phase separation may also be minimised by reducing the particle granule size and adjusting the emulsifier level added. Permissible emulsifiers are mono and diglycerides (0.15-2g /100g) or lecithin.

Thermal treatments

Thermal (heat) treatment processes for microbial log reduction can be applied to LNS-SQ and raw materials contained in LNS-SQ.

Safety

Manufacturers are responsible for assuring that the product does not contain any harmful substance originating from micro-organisms or any other poisonous or deleterious substances, including micro-organisms, heavy metals, pesticides, objectional or foreign matter or anti-nutritional factors, in amounts that may represent a hazard to health. Foreign matter detection is expected to be carried out on the filled sachet.

Quality Assurance

Products must be manufactured in accordance with Codex Alimentarius applicable references, Good Manufacturing Practice (GMPs) and Good Hygiene Practices (GHPs). All producers must have a food safety policy in place and a complete quality management system based on a Hazard Analysis and Critical Control Points (HACCP) approach to food safety. FSSC 22000 certification is highly recommended.

Prerequisite programs including a HACCP plan and environmental monitoring programs must be implemented. Environmental monitoring of sampling sites should be prioritized according to the likelihood of contamination of processing lines and the impact on the product and should be conducted under normal operating conditions. Manufacturers are expected to implement an environmental monitoring program with a four-sanitary zoning system.

Raw material and starting material testing of high-risk ingredients is required.

Microbiological Safety and Testing

The manufacturer establishes safety criteria for production as well as for the finished product based on a risk assessment performed on the raw materials and the processing methods. Raw material testing of high-risk ingredients upon receipt is required. Methods for detection and/or quantification and sampling plan details, including the n, c, m, M, and p. The microbiological criteria should follow the principles specified in the following standards below:

Microbiological tests

The manufacturer is responsible for elaborating an analytical plan for the LNS-SQ paste. All analytical test procedures must be described in sufficient detail, including analysis methods.

ISO 17025-certified laboratories should preferably be used.

Analytical control plans should be detailed and include1: tests for *Salmonella* & Enterobacteriaceae.

Following the sampling plan and recommended method (or alternative validated method) in example (e) in Appendix 1 of the *Codex of Hygienic Practice for Low Moisture Foods* CXC 75 2012, (2016) for Salmonella:

a). Salmonella:

0cfu per 25g

n=30 (× 25 g)

c=0; m=0/25g; 2 class plan1

Method: *ISO 6579; or alternative validated method*

b). Enterobacteriaceae (EB):

10cfu per g maximum

n=10, (×10grams),

c=2, m=10 cfu/g; M=100 cfu/g maximum1.

Method: *AOAC 975.55; AOAC 2003.01; ISO 21528-2, or alternative validated method*

1 Annotations

n = number of units to be taken.

c = the maximum allowable number of defective sample units in a 2-class plan or marginally acceptable sample units in a 3-class plan

m = a microbiological limit which, in a 2-class plan, separates good quality from defective quality or, in a 3-class plan, separates good quality from marginally acceptable quality

M = a microbiological limit which, in a 3-class plan, separates marginally acceptable quality from defective quality.

P = class plan

Pesticides, Heavy metals, and other Contaminants

Verifying that pesticide and heavy metals levels are below accepted limits is the responsibility of the manufacturer. Examples of mycotoxins, pesticides and heavy metals that must be controlled, include, but are not limited to:

Mycotoxins: Aflatoxin: 10µg/ kg max

Heavy metals: Arsenic, Cadmium, Lead, Mercury

Pesticides: Carbamates Organochlorine Organophosphorus, Pyrethroid

Radioactivity

Radioactive compound may contaminate foods if grown in soils contaminated from nuclear accidents or if ionizing radiation is used as preservation method. This risk is best managed by using only ingredients certified free of radioactivity. The nuclear radiation level should meet the values valid in the area of consumption.

Melamine

The level of melamine must not exceed 1 mg/kg in milk products.

Traceability

A complete traceability system must be in place. For every batch number, the manufacturer must be able to find all the history of the finished products (composition, raw materials used, processing parameters, analytical results, quantity produced and dispatched, customer sites delivered, etc.).

Packaging and Labelling

PACKAGING

Refer to the special conditions of contract and applicable labelling regulations and standards for guidance on packaging.

LABELLING

Labelling should adhere to the applicable labelling regulations and other applicable standards

- In addition to the requirements of the applicable Regulations and the Regulations relating to the Labelling and Advertising of Foodstuffs, the label of the product should comply with the labelling requirements of the Regulations Relating to Foodstuffs for Infants and Young Children (Government Notice No. R.991 of 6 December 2012).

Specifications Primary packaging

The primary packaging must be portion controlled: each unit of 20 g net. Packaging material can not contain any detachable parts that present a choking hazard. Inks used for marking and glue must be food-contact grade, water, and lipid resistant. The information printed on sachet must be intact by the end of the shelf life, including pre-printed marking as well as date and batch markings. Reverse printing is mandatory. The pouch material must not transfer any element (particle, flavour, or odour) to the product. Packaging material must ensure to withstand pressure changes associated with air transport. Pouches must be free of damage, such as (but not limited to) tears, cuts, holes, abrasions through one or more layers in the pouch material, leakage through any seal, etc. The primary packaging materials must not transfer particle, flavour, or odour to the product. The closure seal must be free of wrinkles, occluded matter, or evidence of entrapped moisture or grease.

Packaging under nitrogen is recommended as it contributes to lengthen product shelf life, i.e., protecting lipid oxidation and vitamins from oxidising.

A comprehensive quality assurance system shall be implemented to cover the sachet seal integrity. This shall include regular checks of the filling parameters (e.g., sealing temperature) in combination with a visual inspection of the sealing and a leak test. This shall be complemented by an additional quality control system for microleaks.

Primary Packaging composition preferred

Packaging specification: 12micron PET/12micron METPET/40micron NylonPE or 40-micron LLDPE, with minimum thickness 60 microns or equivalent.

Example of Applicable standard and test for barrier properties:

WVTR <1.5 g/m2.day (38°C/90% RH) (ASTM F1249-13 or equivalent)

OTR < 2 cc/m2.day (23°C/50% RH) (ASTM F1927-14 or equivalent)

- Generic Name: LNS-SQ
- Lipid-based Nutrient supplement- Small Quantity
- Fortified complementary food
- Supports the prevention of undernutrition in infants and young children age 6 to 23 months and older

Secondary packaging

Cartons should be strong and sturdy, allowing stacking up to 2.4m high, resistant to puncturing and provide protection of the goods for carriage by air, sea and/or road to final destinations worldwide, including remote locations under adverse climatic and storage conditions and high humidity.

Cartons should be stacked on pallets and secured in the transportation vessel in a way that prevents movement during transportation. Pallets should be wrapped with plastic wrap to protect goods from contamination and movement of cartons during shipment.

Following requirements apply

ECT (Edge Crush Test) >11kN/m with minimum 60% remaining with 90% humidity at the highest recommended temperature of storage. Manufacturers are required to choose suitable carton strength that is appropriate for domestic or export transportation. Cartons should be protected by isolating sachets inside the carton in a plastic bag to prevent damaging other cartons in case of possible leakage.

7. CATEGORY SEVEN: NUTRITION SUPPLEMENTS FOR MALNOURISHED PATIENTS

7.1. INSTANT MAIZE-BASED CEREAL PRODUCT FOR OLDER INFANTS AND YOUNG CHILDREN

Description: Instant maize-based cereal product with added protein which is prepared for consumption with water or other appropriate protein-free liquid. The product is wheat-free, gluten-free, egg-free and maize based for infants and young children from the age of 6 months up to the age of three years (36 months).

Indication for Use: the product is intended to be used as a nutritional supplement to supply additional energy and nutrients to the staple foods used for the feeding of older infants and young children as part of a progressively diversified diet.

Packaging

Item number: RT9-07-001 In 50g sachets
Item number: RT9-07-002 In 1kg re-sealable foil packet (include a graded scoop as per reconstituted instructions)

Generic Name: Instant Maize-based Cereal for Infants and Young Children
Clear Statement: A Complementary Food for Older infants and young children from the age of 6 months up to the age of three years (6 - 36 months).

TECHNICAL SPECIFICATIONS

QUALITY AND SAFETY FACTORS

- The product shall comply, in terms of raw materials, composition or manufacture, except when specified otherwise in the contract, with the following regulations, guidelines, or standards of Codex Alimentarius:
    - Regulations relating to Foodstuffs for Infants and Young Children (Government Notice No. R.991 of 6 December 2012)
    - Guidelines on Formulated Supplementary Foods for Older Infants and Young Children, CAC/GL
      08-1991 of the Codex Alimentarius.
    - Codex standard for processed cereal-based foods for infants and young children. CODEX STAN
      074-1981, Rev. 1-2006, of the Codex Alimentarius.
    - General principles for addition of essential nutrients to foods: CAC/GL 09-1987 (amended 1989,
      1991), of the Codex Alimentarius.

Raw Materials

- All ingredients, including optional ingredients, shall be clean, safe, suitable and of good quality.
- Maize and other cereals used in the formulation of the product should be processed in such a way as to reduce the fibre content, when necessary, and to eliminate tannins or other phenolic materials which can lower protein digestibility.

- All processing and drying should be carried out in a manner that minimizes loss of nutritive value, particularly protein quality.
- The moisture content of the products shall be governed by good manufacturing practice for the individual product categories and shall be at such a level that there is a minimum loss of nutritive value and at which microorganisms cannot multiply.
- The product is prepared primarily from maize. The requirements concerning energy and nutrients refer to the product ready for use as marketed or prepared according to the instructions of the manufacturer, unless otherwise specified.

- The product shall be manufactured from fresh maize grain of good quality, free from foreign materials, substances hazardous to health, excessive moisture, insect damage and fungal contamination and shall comply with all relevant regulations on maize and standards.

- Maize must also comply with CXS 153-1985 and be tested for aflatoxin (recommended method AACC 45-05 or AOAC 26.049/1984).

- Maize must be stored under dry, ventilated, and hygienic conditions.

Consistency and Particle Size

- When prepared according to the label directions for use, the product should have a texture appropriate for the spoon feeding of older infants or young children.

Specific Prohibition

- The product and its components shall not have been treated by ionizing radiation. The use of partially hydrogenated fats for these products is prohibited.

Additional Requirements

- The product shall be processed as a pre-cooked food under conditions which permit improvements in the digestibility of starches and proteins.
- Finished product must have a pleasant smell and palatable taste.
- It shall have a uniform fine texture and be free from lumping or balling when mixed with water of ambient temperature.

Optional ingredients

- Products containing honey or maple syrup should be processed in such a way as to destroy spores of *Clostridium botulinum*, if present.
- Only L(+) lactic acid producing cultures may be used.

Flavours

- The following flavours may be used:
    - Natural fruit extracts and vanilla extracts at GMP level
    - Ethyl vanillin and vanillin: 7 mg/100 g READY-TO-USE

Food Additives

Only the food additives listed in this Section or in the Codex Advisory List of Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) may be present in this product as described in 2.1 of the Codex Stan 074-1981, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

- The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and
- The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good

manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CODEX/STAN 192-1995).

Additives, colourants, flavourings and preservatives used in the manufacturing of the product shall be in accordance with additives, colourants, flavourings and preservatives permitted in the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 and other applicable Codex Alimentarius standards, Guidelines and Codes of practice, with specific reference to **Section 2.1** of the Codex Standard (CODEX STAN 074-1981).

Contaminants

Pesticides Residues

The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain, or, if technically unavoidable, are reduced to the maximum extent possible. These measures shall take into account the specific nature of the products concerned and the specific population group for which they are intended.

Other Contaminants

The product shall be free from residues of hormones, antibiotics as determined by means of agreed methods of analysis and practically free from other contaminants, especially pharmacologically active substances.

Mycotoxins – Product shall comply with those maximum mycotoxin limits established by the applicable regulations and Codex Alimentarius standards.

Technologies For and Effects of Processing

- Cereals, pulses and oilseeds should first be treated to obtain wholesome and clean raw materials of good quality.
- Such treatments for these ingredients is stipulated in Section 5 of the Codex Alimentarius ***Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 08-1991***).

COMPOSITIONAL REQUIREMENTS

Energy

The energy density of the food can be increased by:

- the addition of fats and oils, and/or digestible carbohydrates including, in moderation, sugars; and/or,
- processing the basic ingredients as indicated in Section 5 of CAC/GL 08-1991).

Proteins

- Cereals, legumes and/or oilseed flours, alone or preferably mixed, can constitute an appropriate source of proteins, provided they are prepared in such a way that in the finished product the proteins in the mixture satisfy the criteria below.
- The amino-acid score[1] (previously called the chemical score) corrected in accordance with the true digestibility of the crude proteins, should not be less than 70 per cent of that of casein. Higher values should be required if calculation of the score was based not, as is usually the case,

[1] The amino acid score is the ratio between the quantity of limiting amino acid in the protein tested and the quantity of the same amino acid in the reference protein: 100 x (mg of the limiting amino acid in 1 g of the protein tested)/(mg of the same amino acid in 1 g of the protein with the reference amino acid profile).

on the most limiting amino acid[2], but on two or more key amino acids such as lysine, methionine, cystine, threonine and tryptophan.

- If, for technical reasons, the amino acid score and the digestibility of a protein cannot be determined, the protein quality should be measured by biological assays. Alternatively, the protein quality may be computed from published data on essential amino acid patterns of dietary proteins and their digestibility. The addition of methionine, lysine, tryptophan or other limiting amino acids, solely in the L-form (except for DL-methionine, should be contemplated only when, for economic and technological reasons, no mixture of vegetable and/or animal proteins makes it possible to obtain an adequate protein quality.

Carbohydrates

- Starch is likely to be a major constituent of the product. To ensure that its energy value is realized, this starch should be provided in a readily digestible form.
- Guidance on increasing the digestibility of starches is given in Section 5 of CAC/GL 08-1991.
- Dietary fibres and other non-absorbable carbohydrates are partially fermented by the intestinal flora to produce short-chain fatty acids, lactate and ethanol which may subsequently be absorbed and metabolized. Increasing the intake of dietary fibres enhances stool bulk. They also may affect the efficiency of absorption of various nutrients of significance in diets with a marginal nutrient content, so the dietary fibre content of the product should be reduced to a level not exceeding 5 g per 100 g.
- If sucrose, fructose, glucose, glucose syrup or honey are added to products:
    - the amount of added carbohydrates from these sources shall not exceed 1.2 g/100 kJ (5 g/100 kcal);
    - the amount of added fructose shall not exceed 0.6 g/100 kJ (2.5 g/100 kcal).

Vitamins and/or minerals

- Vitamins and/or minerals added should be selected from the Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979).

Table 1: Nutritional Composition per 100g

Nutritional Composition	Unit	Minimum	Maximum
Energy	kJ	330	1680
Protein	g	4.3	14
Fat	g	3.6	13
Carbohydrate	g	5.9	55.0
Sodium	mg		<403.2
Calcium	mg	>200.0	
Vitamin A	mcg RE	46.2	722.4
Vitamin D	mcg	0.83	12.6
Vitamin B1	mcg	>41.3	
Iron	mg	1.2	8.0
Dietary Fibre	g		<5g

[2] The limiting amino acid is the essential amino acid present in the lowest proportion as compared with the quantity of this amino acid in the reference protein.

ANALYTICAL REQUIREMENTS

The principal tests listed below must be performed in order to check if the quality of the product meets above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Nutritional Composition	Limit per 100g	Reference method
Energy	330-1680	
Protein	4.3-14g	AOAC 981.10
Fat	3.6-13g	AOAC 954.02
Crude fibre	<5g	AOAC 962.09
Vitamin A	46.2-722.4mcgRE	AOAC 992.04
Iron	1.2-8.0mg	AOAC 944.02
Calcium	>200mg	AOAC 984.27
Aflatoxin (total)	Max. 20 ppb (total of B1, B2, G1, G2)	AOAC 972.26
Deoxynivalenol (DON)	Max. 1.0 mg/kg (dry matter basis)	EN 15891:2010
Mesophilic aerobic bacteria	< 100,000 cfu/g	ICC No 125
Coliforms	< 100 cfu/g	AOAC 2005.03
Salmonella	0 cfu/25g	AACC 42-25B
Escherichia Coli	< 10 cfu/g	AOAC 991.14
Staphylococcus aureus	< 10 cfu/g	AACC 42-30B
Bacillus cereus	< 50 cfu/g	AOAC 980.31
Yeasts and moulds	< 1,000 cfu/g	ICC No 146

Shelf life

The product shall retain the above-mentioned specifications for the duration of the shelf life indicated by the manufacturer when stored in dry conditions at a temperature of 30 degrees Celsius supported by real time shelf-life data. Shelf-life studies shall be conducted in accordance with the requirements stipulated in the special conditions of contract. Follow the WHO standards for stability studies.

5. PACKAGING

Refer to the special conditions of contract and applicable labelling regulations and standards for guidance on packaging.

LABELLING

Labelling should adhere to the applicable labelling regulations and other applicable standards

- In addition to the requirements of the applicable Regulations and the Regulations relating to the Labelling and Advertising of Foodstuffs, the label of the product should comply with the labelling requirements of the Regulations relating to Foodstuffs for Infants and Young Children (Government Notice No. R.991 of 6 December 2012).

7.2. INSTANT ENRICHED PORRIDGE (4 YEARS AND OLDER)

Description: Instant enriched porridge is a corn soya blended product from 4 years onwards. It is prepared from heat-treated maize and soya beans, vitamins, and minerals. The product shall be processed as a pre-cooked product under conditions which permit improvements in the digestibility of starches and proteins and in particular the deactivation of trypsin inhibitors in soya as indicated by the urease test. Preferred heat treatments include wet extrusion, dry extrusion and drum drying.
Note: Roasre-sealable ting is not acceptable.

Indications for Use: In patients 4 years and older with increased nutritional requirements or inadequate food intake.

Packaging

Item number: RT9-07-003 In 50g sachet
Item number: RT9-07-004 In 1 kg re-sealable container, assorted flavours (include a graded scoop as per reconstituted instructions)

Generic Name: Instant Enriched porridge
Clear Statement: Nutrition supplement for adults and children older than 4 years.

TECHNICAL SPECIFICATION

Applicable Standards

- Instant enriched porridge shall comply, in terms of raw materials, composition or manufacture, except when specified otherwise in the contract, with the following regulations, guidelines, or standards of Codex Alimentarius.
- Regulations relating to the Application of Hazard Analysis and Critical Control Point System, (Government Notice No. R.908 of 27 June 2003),
- Recommended International Code of Practice: General Principles of Food Hygiene CAC/RCP 1-1969 Rev 4 - 2003 including Annex “Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its application”.
- General principles for addition of essential nutrients to foods: CAC/GL 09-1987 (amended 1989,
  1991), of the Codex Alimentarius.

Raw Materials: Main Ingredients

- Instant enriched porridge shall be manufactured from fresh maize grain of good quality, free from foreign materials, substances hazardous to health, excessive moisture, insect damage and fungal contamination and shall comply with all relevant regulations on maize and standards. Maize must also comply with CXS 153-1985 and be tested for aflatoxin (recommended method AACC 45-05 or AOAC 26.049/1984).
- Soya beans must conform to the codex standard 171 of 1989.
- Maize and soya beans must be stored under dry, ventilated and hygienic conditions.
- Only safe insecticides may be used for fumigation control.
- Where needed fumigation must be provided by certified service providers.

Additional Requirements

- Instant enriched porridge shall be processed as a pre-cooked food under conditions which permit improvements in the digestibility of starches and proteins.
- Finished product must have a pleasant smell and palatable taste.
- It shall have a uniform fine texture and be free from lumping or balling when mixed with water of ambient temperature.
- Additives, colourants, flavourings and preservatives used in the manufacturing of instant enriched porridge shall be in accordance with additives, colourants, flavourings and preservatives permitted in the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 and other applicable Codex Alimentarius standards.

Contaminants

- ***Heavy metals*** – Product shall be free from heavy metals in amounts which may represent a hazard to health.
- ***Pesticide residues*** – Product shall comply with those maximum residue limits established by the applicable regulations and Codex Alimentarius Commission. Shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain, or, if technically unavoidable, are reduced to the maximum extent possible. These measures shall take into account the specific nature of the products concerned and the specific population group for which they are intended.
- ***Mycotoxins*** – Product shall comply with those maximum mycotoxin limits established by the applicable regulations and Codex Alimentarius standards. When tested by appropriate methods of sampling and examination, the product shall be free from micro-organisms in amounts which may represent a hazard to health, shall be free from parasites which may represent a hazard to health; and shall not contain any susbstance originating from micro-organisms in amounts which may represent a hazard to health.

Vitamins and Minerals

- Manufacturers can purchase the vitamins and minerals compounds or the premix from any supplier that implements Good Manufacturing Practice and HACCP systems.

Processing

- To ensure that the nutritional targets of finished product are fully met, the manufacturer should check the quality of incoming materials i.e., fat and protein contents of soya and if necessary make adjustments as required.

Shelf life

- The product shall retain the above-mentioned specifications for the duration of the shelf life indicated by the manufacturer when stored in dry conditions at a temperature of 30 ◦C supported by real time shelf-life data. Shelf-life studies shall be conducted in accordance with the requirements stipulated in the special conditions of contract. Follow the WHO standards for stability studies.

Packaging

- Refer to the special conditions of contract and applicable labelling regulations and standards for guidance on packaging.

Table 1: Nutritional Composition per 100g

Nutritional Composition	Unit	Minimum	Maximum
Energy	kJ	1500	1800
Protein	g	10	20
Fat	g	10	25
Vitamin A	mcgRE	900	1200
Vitamin B1	mg	0.5	1.5
Vitamin B2	mg	0.5	1.5
Niacin	mg	5.0	20
Vitamin B6	mg	0.5	2.0
Vitamin B12	mcg	1.0	2.0
Vitamin C	mg	80	150
Folic Acid	mcg	100	400
Iron	mg	2.0	10
Zinc	mg	2.0	5.0
Selenium	mcg	30	60
Biotin	mcg	5.0	10
Iodine	mcg	20	40
Vitamin D	mcg	5.0	20
Vitamin E	mg	5.0	10
Pantothenic Acid	mg	1.0	2.0
Calcium	mg	300	1000
Potassium	mg	100	140
Phosphorus	mg	200	280

Analytical Requirements

The principal tests listed below must be performed in order to check if the quality of the product meets the above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the right to request additional analyses in case of future quality assessment.

List of Compulsory Tests

Tests	Analytical requirements	Reference method
Energy	1500-1800KJ	
Protein	10-20g	AOAC 981.10
Fat	10-25g	AOAC 954.02
Vitamin A	900-1200mcgRE	AOAC 992.04
Iron	2.0-10mg	AOAC 944.02
Calcium	300-1000mg	AOAC 984.27
Potassium	100-140mg	AOAC 984.27
Aflatoxin (total)	Max. 20 ppb (total of B1, B2, G1, G2)	AOAC 972.26
Deoxynivalenol (DON)	Max. 1.0 mg/kg (dry matter basis)	EN 15891:2010
Mesophilic aerobic bacteria	< 100,000 cfu/g	ICC No 125
Coliforms	< 100 cfu/g	AOAC 2005.03
Salmonella	0 cfu/25g	AACC 42-25B
Escherichia Coli	< 10 cfu/g	AOAC 991.14
Staphylococcus aureus	< 10 cfu/g	AACC 42-30B
Bacillus cereus	< 50 cfu/g	AOAC 980.31
Yeasts and moulds	< 1,000 cfu/g	ICC No 146

7.3. ENRICHED SUPPLEMENTARY DRINK FOR ADULTS AND CHILDREN OLDER THAN 10 YEARS

Description: Enriched supplementary drink, low in lactose and gluten free.

Indication for Use: Enriched supplementary drink for adults and children older than 10 years.

Packaging

Item number: RT9-07-005 In 75g-100g sachet (packed in a box of 10)
Item number: RT9-07-006 1 kg re-saleable container (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutrients and nutritional values per 100ml finished product	Unit	Minimum	Maximum
Energy	kJ	300	400
Protein	G	2.5	4.0
Carbohydrates	G	10.0	12.0
Fat	G	1.2	3.6
Vitamin A	mcgRE	140	180
Vitamin B1	mg	0.1	0.5
Vitamin B2	mg	0.1	0.5

Nutrients and nutritional values per 100ml finished product	Unit	Minimum	Maximum
Niacin	mg	2.0	3.5
Vitamin B6	mg	0.2	0.4
Vitamin B12	mcg	0.3	0.5
Vitamin C	mg	15	20
Folic Acid	mcg	60	80
Iron	mg	1.4	2.0
Zinc	mg	1.0	1.5
Selenium	mcg	5.0	6.0
Vitamin D	mcg	2.0	3.0
Calcium	mg	200	260
Potassium	mg	120	160
Sodium	mg		<96

The principal tests listed below must be performed in order to check if the quality of the product meets above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Tests	Analytical requirements	Reference method
Energy	300-400KJ	
Protein	2.5-4.0g	AOAC 981.10
Fat	1.2-3.6g	AOAC 954.02
Vitamin A	140-180mcgRE	AOAC 992.04
Iron	1.4-2.0mg	AOAC 944.02
Calcium	200-260mg	AOAC 984.27
Potassium	120-160mg	AOAC 984.27
Aflatoxin (total)	Max. 20 ppb (total of B1, B2, G1, G2)	AOAC 972.26
Deoxynivalenol (DON)	Max. 1.0 mg/kg (dry matter basis)	EN 15891:2010
Mesophilic aerobic bacteria	< 100,000 cfu/g	ICC No 125
Coliforms	< 100 cfu/g	AOAC 2005.03
Salmonella	0 cfu/25g	AACC 42-25B
Escherichia Coli	< 10 cfu/g	AOAC 991.14
Staphylococcus aureus	< 10 cfu/g	AACC 42-30B
Bacillus cereus	< 50 cfu/g	AOAC 980.31
Yeasts and moulds	< 1,000 cfu/g	ICC No 146

7.4 SUPPLEMENTARY DRINK FOR CHILDREN 1-10 YEARS

Description: Enriched supplementary drink, low in lactose and gluten free.

Indication for Use: Enriched supplementary drink for children 1-10 years.

Packaging

Item number: RT9-07-007 In 25-50g sachet
Item number: RT9-07-008 In 1 kg re-sealable container (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutrients and nutritional values per 100ml finished product	Unit	Minimum	Maximum
Energy	kJ	418	450
Protein	G	3.0	4.0
Carbohydrates	G	10.0	16.0
Fat	G	2.5	4.0
Vitamin A	mcgRE	60.0	80.0
Vitamin B1	mg	0.1	0.5
Vitamin B2	mg	0.1	0.5
Niacin	mg	1.5	2.0
Vitamin B6	mg	0.1	0.5
Vitamin B12	mcg	0.1	0.5
Vitamin C	mg	8.0	12.0
Folic Acid	mcg	40.0	55.0
Iron	mg	1.5	2.0
Zinc	mg	1.0	1.5
Selenium	mcg	5.5	6.0
Vitamin D	mcg	1.2	1.8
Calcium	mg	100	150
Potassium	mg	120	160
Sodium	mg	40	60.0

The principal tests listed below must be performed in order to check if the quality of the product meets above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the right to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Tests	Analytical requirements	Reference method
Energy	418-450KJ	
Protein	3.0-4.0g	AOAC 981.10
Fat	2.5-4.0g	AOAC 954.02
Vitamin A	60-80mcgRE	AOAC 992.04
Iron	1.5-2.0mg	AOAC 944.02
Calcium	100-150mg	AOAC 984.27
Potassium	120-160mg	AOAC 984.27
Aflatoxin (total)	Max. 20 ppb (total of B1, B2, G1, G2)	AOAC 972.26
Deoxynivalenol (DON)	Max. 1.0 mg/kg (dry matter basis)	EN 15891:2010
Mesophilic aerobic bacteria	< 100,000 cfu/g	ICC No 125
Coliforms	< 100 cfu/g	AOAC 2005.03
Salmonella	0 cfu/25g	AACC 42-25B
Escherichia Coli	< 10 cfu/g	AOAC 991.14
Staphylococcus aureus	< 10 cfu/g	AACC 42-30B
Bacillus cereus	< 50 cfu/g	AOAC 980.31
Yeasts and moulds	< 1,000 cfu/g	ICC No 146

7.5 ENRICHED SUPPLEMENTARY ACIDIFIED DRINK FOR ADULTS AND CHILDREN OLDER THAN 1 YEAR

Description: Enriched supplementary acidified drink with a PH of ≤5. Soy sources are not accepted due to high content of anti-nutrients, with the exception of soy isolate.

Indication for Use: Enriched supplementary acidified drink for adults and children older than 1 year.

Packaging

Item number: RT9-07-009 In 200ml – 300ml container (excluding re-tort pouches)
Item number: RT9-07-010 In 1kg re-sealable container (include a graded scoop as per reconstituted instructions)

Containing per 100ml:

Nutrients and nutritional values per 100ml finished product	Unit	Minimum	Maximum
Energy	kJ	400	550
Protein	g	3.0	4.0
Carbohydrates	g	10.0	15.0
Fat	g	3.0	4.0
Vitamin A	mcgRE	140	180
Vitamin B1	mg	0.1	0.5
Vitamin B2	mg	0.1	0.5

Nutrients and nutritional values per 100ml finished product	Unit	Minimum	Maximum
Niacin	mg	2.0	4.5
Vitamin B6	mg	0.2	0.5
Vitamin B12	mcg	0.3	0.6
Vitamin C	mg	20	40
Folic Acid	mcg	60	80
Iron	mg	1.5	2.5
Zinc	mg	1.0	1.5
Selenium	mcg	6.0	8.0
Vitamin D	mcg	1.5	2.0
Calcium	mg	200	250
Potassium	mg	120	160
Sodium	mg	50	100

The principal tests listed below must be performed in order to check if the quality of the product meets above requirements. The validated method of analysis used must be indicated with the test results. The Department of Health reserves the rights to request for additional analyses in case of future quality assessment.

List of Compulsory Tests

Tests	Analytical requirements	Reference method
Energy	400-550KJ	
Protein	3.0-4.0g	AOAC 981.10
Fat	3.0-4.0g	AOAC 954.02
Vitamin A	140-180mcgRE	AOAC 992.04
Iron	1.5-2.5mg	AOAC 944.02
Calcium	200-250mg	AOAC 984.27
Potassium	120-160mg	AOAC 984.27
Aflatoxin (total)	Max. 20 ppb (total of B1, B2, G1, G2)	AOAC 972.26
Deoxynivalenol (DON)	Max. 1.0 mg/kg (dry matter basis)	EN 15891:2010
Mesophilic aerobic bacteria	< 100,000 cfu/g	ICC No 125
Coliforms	< 100 cfu/g	AOAC 2005.03
Salmonella	0 cfu/25g	AACC 42-25B
Escherichia Coli	< 10 cfu/g	AOAC 991.14
Staphylococcus aureus	< 10 cfu/g	AACC 42-30B
Bacillus cereus	< 50 cfu/g	AOAC 980.31
Yeasts and moulds	< 1,000 cfu/g	ICC No 146

8. CATEGORY EIGHT: FEEDING SYSTEMS

8.1. Tube Feed Bottle

Description: Bottle for enteral use must be universal and must fit on any set. Bottle must be calibrated in 100 ml units with a screw top and hanger. Bottle must be autoclavable at a temperature of 115 ^{o}C and should be BPA free. Bottle must be able to hang upside down (enteral feeding). Grading must be moulded and not printed. Grading must indicate volume of content when the bottle stands upright and when it hangs upside down. Must have no sharp corners inside so that it is easily cleaned. Compatible with Enfit feeding systems.

Indication for Use: Enteral feed bottle used for the administration of feeds to adults and children.

Packaging
Item number: RT9-08-001 500ml plastic bottle

8.2. Feeding Cup System

Description: The main holder and feeding cup should be from virgin high-grade polypropylene material. The unit must withstand autoclaving at a temperature of 115 ^{o}C. The main holder must hold 200ml and have volume calibrations marked every 25 ml. The feeding cup must hold 50 to 60ml. All the components should have no sharp edges and the surface texture should be smooth. The lid must fit watertight on the main holder. The inner and outer surface of the different components must be reachable by hand and/or finger in order to clean. The feeding cup must be able to be stored inside the main holder with the lid in place. BPA free. The unit must be individually packaged and sealed in a plastic bag with an illustrated leaflet printed.

Indication for Use: Feeding cup for feeding neonates and infants.

Packaging
Item number: RT9-08-002 Per unit (Main holder, lid for the main holder and the feeding cup)

8.3. FEEDING CUP FEEDING CUP

Description: The feeding cup should be from virgin high-grade polypropylene material. The unit must withstand autoclaving at a temperature of 115 ^{o}C. The feeding cup must hold 50 to 60ml. All the components should have no sharp edges, and the surface texture should be smooth. The inner and outer surface of the different components must be reachable by hand and/or finger in order to clean. BPA free.

Indication for Use: Feeding cup for feeding neonates and infants.

Packaging

Item number: RT9-08-003 Per unit (Feeding cup)

8.4. TUBE FEED BOTTLE FOR INFANTS

Description: Size 125ml and 250ml. Must be compatible with universal enteral feeding sets. Bottle must be calibrated in 10ml units with a screw top and hanger. Must be made from transparent material, high-grade polypropylene material, able to withstand freezing, pasteurization, autoclaving up to **115°C**, boiling and exposure to the sun. BPA free. The shape must NOT replicate a standard **formula feeding bottle.** Bottle must be able to hang upside down (enteral feeding). Must fit into readily used pasteurizers. Grading must be moulded and not printed. Grading must indicate volume of content when the bottle stands upright and when it hangs upside down. Must have no sharp corners inside so that it is easily cleaned. Compatible with Enfit feeding systems.

Indication for Use: Enteral feeding bottle for infants. For storage of paediatric enteral feeds and expressed breastmilk. Enteral Feed bottle that can be used in the administration of for enteral feed for infants and young children as well as to store and process expressed human breastmilk in a human breastmilk bank.

Packaging

Item number: RT9-08-004 In 250ml enteral feeding bottle with screw-on top and hanger
Item number: RT9-08-005 In 125ml enteral feeding bottle with screw-on top and hanger