RT9-1-2020 DETAILED SPECIFICATIONS

CATEGORY ONE: INFANT FEEDS

1.2 BREASTMILK FORTIFIER FOR PREMATURE AND/OR LOW BIRTH 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 no: 42231802-00160 In 1g sachet

Item no: 42231802-00161 In 200g container (0.25g scoop)

Containing per 1g

	Minimum	**Maximum**
Energy	15KJ	20KJ
Protein	0.2g	0.5g
Carbohydrate	0.2g	0.75g
Fat	0g	0.2g
Vitamin A	65mcgRE	120mcgRE
Vitamin D	1mcg	3.5mcg
Calcium	10mg	25mg
Iron		0.5mg
Sodium	3mg	10mg
Phosphorous	10mg	19mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	**LIMIT PER 1G**	
	Minimum	**Maximum**
Energy	15KJ	20KJ
Protein	0.2g	0.5g
Vitamin A	65mcgRE	120mcgRE
Vitamin D	1mcg	3.5mcg
Calcium	10mg	25mg
Iron		0.5mg

Sodium	3mg	10mg
Phosphorous	10mg	19mg

Microbiological tests:

Microbiological criteria should be established in the context of risk management options and in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXC 21-97). The manufacturer is responsible to elaborate an analytical plan for the finished products mentioned above. 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* & *Enterobacter Sakazakii*. Following the sampling plan and recommended method (or alternative validated method) as detailed in Annex I of the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008) for *Salmonella:* Method: ISO 6579 and for *Enterobacter Sakazakii*: Method: ISO/TS 22964:2006.

Table: Microbiological Criteria

Microorganisms	**N**	**C**	**m**	**Class Plan**
**Salmonella*	60	0	0/25 g	2
***Enterobacter Asakazakii*	30	0	0/10 g	2

Where

- n: number of samples that must conform to the criteria
- c: the maximum allowable number of defective sample units in a 2-class plan
- m: a microbiological limit which, in a 2-class plan, separates good quality from defective quality

*The mean concentration detected is 1 cfu in 526g (if the assumed standard deviation is 0.8 and probability of detection is 95%).
**The mean concentration detected is 1 cfu in 340g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 100g (if the assumed standard deviation is 0.5 and probability of detection is 99%)

Applicable Reference: the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008).

1.3 STARTER FORMULA FOR INFANTS (WHEY DOMINANT)

Description: Whey dominant starter 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 probiotics may be used. L (+) Lactic acid producing cultures for the purpose of acidifying the formula may be used.

Packaging

Item no: 42231802-00162 In 400-450g container

Item no: 42231802-00163 In 50ml-100ml RTU container

Item no: 42231802-00164 In 150ml-200ml RTU container

Containing per 100ml

	Minimum	**Maximum**	**Upper Limit**
Energy	250KJ	295KJ	
Protein	1.1g	2.1g	
Whey Protein	>0.66g		
Carbohydrate	5.5g	9.7g	
Fat	2.6g	4.1g	
Vitamin A	38.5mcgRE		127mcgRE
Vitamin D	0.66mcg	1.77mcg	
Vitamin E	0.33mgαTE		3.54mgαTE
Vitamin K	2.75mcg		19.18mcg
Vitamin C	6.82mg		50mg
Vitamin B1	38.5mcg		212mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	52.3mcg		351mcg
Vitamin B6	23.1mcg		132mcg
Vitamin B12	0.07mcg		1.17mcg
Folic Acid	6.77mcg		35.4mcg
Calcium	33mg		103mg
Iron	0.27mg		1.0mg
Sodium	13.75mg	37.17mg	
Zinc	0.33mg		1.06mg

Phosphorus	16.5mg		70.8mg
Magnesium	3.3mg		10.62mg
Potassium	38.5mg	114.17mg	

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML		
	Minimum	**Maximum**	**Upper Limit**
Energy	250KJ	295KJ	
Protein	1.1g	2.1g	
Whey Protein	>0.66g		
Carbohydrate	5.5g	9.7g	
Fat	2.6g	4.1g	
Vitamin A	38.5mcgRE		127mcgRE
Vitamin D	0.66mcg	1.77mcg	
Vitamin E	0.33mgαTE		3.54mgαTE
Vitamin K	2.75mcg		19.18mcg
Vitamin C	6.82mg		50mg
Vitamin B1	38.5mcg		212mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	52.3mcg		351mcg
Vitamin B6	23.1mcg		132mcg
Vitamin B12	0.07mcg		1.17mcg
Folic Acid	6.77mcg		35.4mcg
Calcium	33mg		103mg
Iron	0.27mg		1.0mg
Sodium	13.75mg	37.17mg	
Zinc	0.33mg		1.06mg
Phosphorus	16.5mg		70.8mg
Magnesium	3.3mg		10.62mg
Potassium	38.5mg	114.17mg	

Microbiological tests:

Microbiological criteria should be established in the context of risk management options and in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXC 21-97). The manufacturer is responsible to elaborate an analytical plan for the finished products

mentioned above. 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* & *Enterobacter Sakazakii*. Following the sampling plan and recommended method (or alternative validated method) as detailed in Annex I of the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008) for *Salmonella:* Method: ISO 6579 and for *Enterobacter Sakazakii*: Method: ISO/TS 22964:2006.

Table: Microbiological Criteria

Microorganisms	**N**	**C**	**m**	**Class Plan**
**Salmonella*	60	0	0/25 g	2
***Enterobacter Asakazakii*	30	0	0/10 g	2

Where

- n: number of samples that must conform to the criteria
- c: the maximum allowable number of defective sample units in a 2-class plan
- m: a microbiological limit which, in a 2-class plan, separates good quality from defective quality

*The mean concentration detected is 1 cfu in 526g (if the assumed standard deviation is 0.8 and probability of detection is 95%).
**The mean concentration detected is 1 cfu in 340g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 100g (if the assumed standard deviation is 0.5 and probability of detection is 99%)

Applicable Reference: the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008).

1.4 HIGH PROTEIN FORMULA FOR INFANTS

Description: High protein feed containing 1kcal/ml.

Indication for Use: Feed for infants with increased nutritional 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 probiotics may be used. L (+) Lactic acid producing cultures for the purpose of acidifying the formula may be used.

Packaging

Item no: 42231802-00168 In 120-200ml RTU container

Item no: 42231802-00170 In 400-500g container

Containing per 100ml

	Minimum	Maximum	Upper Limit
Energy	420KJ	450KJ	
Protein	2.08g	2.84g	
Carbohydrate	10.16g	13.37g	
Fat	4.84g	5.67g	
Vitamin A	64.68mcgRE	174.15mcgRE	
Vitamin D	1.16mcg	2.43mcg	
Vitamin E	0.55mgαTE		5.4mgαTE
Vitamin K	4.62mcg		29.25mcg
Vitamin C	11.55mg		76.5mg
Vitamin B1	64.68mcg		324mcg
Niacin	323.4mcg		1620mcg
Vitamin B2	87.78mcg		535.5mcg
Vitamin B6	39.27mcg		202.5mcg
Vitamin B12	0.12mcg		1.62mcg
Folic Acid	11.55mcg		54mcg
Calcium	55.44mg		157.5mg
Iron	0.46mg		1.0mg
Sodium	23.1mg	56.7mg	
Zinc	0.55mg		1.62mg
Phosphorus	27.72mg		108mg
Magnesium	5.54mg		16.2mg
Potassium	64.71mg	174.15mg	

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML		
	Minimum	**Maximum**	**Upper Limit**
Energy	420KJ	450KJ	
Protein	2.08g	2.84g	
Carbohydrate	10.16g	13.37g	
Fat	4.84g	5.67g	
Vitamin A	64.68mcgRE	174.15mcgRE	
Vitamin D	1.16mcg	2.43mcg	
Vitamin E	0.55mgαTE		5.4mgαTE
Vitamin K	4.62mcg		29.25mcg
Vitamin C	11.55mg		76.5mg
Vitamin B1	64.68mcg		324mcg
Niacin	323.4mcg		1620mcg
Vitamin B2	87.78mcg		535.5mcg
Vitamin B6	39.27mcg		202.5mcg
Vitamin B12	0.12mcg		1.62mcg
Folic Acid	11.55mcg		54mcg
Calcium	55.44mg		157.5mg
Iron	0.46mg		1.0mg
Sodium	23.1mg	56.7mg	
Zinc	0.55mg		1.62mg
Phosphorus	27.72mg		108mg
Magnesium	5.54mg		16.2mg
Potassium	64.71mg	174.15mg	

Microbiological tests:

Microbiological criteria should be established in the context of risk management options and in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXC 21-97). The manufacturer is responsible to elaborate an analytical plan for the finished products mentioned above. 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* & *Enterobacter Sakazakii*. Following the sampling plan and recommended method (or alternative validated method) as detailed in Annex I of the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008) for *Salmonella:* Method: ISO 6579 and for *Enterobacter Sakazakii*: Method: ISO/TS 22964:2006.

Table: Microbiological Criteria

Microorganisms	N	C	m	Class Plan
**Salmonella*	60	0	0/25 g	2
***Enterobacter Asakazakii*	30	0	0/10 g	2

Where

- n: number of samples that must conform to the criteria
- c: the maximum allowable number of defective sample units in a 2-class plan
- m: a microbiological limit which, in a 2-class plan, separates good quality from defective quality

*The mean concentration detected is 1 cfu in 526g (if the assumed standard deviation is 0.8 and probability of detection is 95%).
**The mean concentration detected is 1 cfu in 340g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 100g (if the assumed standard deviation is 0.5 and probability of detection is 99%)

Applicable Reference: the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008).

1.5 ELEMENTAL FORMULA FOR INFANTS

Description: Hypoallergenic, elemental formula, 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 and multiple food 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 probiotics may be used. L (+) Lactic acid producing cultures for the purpose of acidifying the formula may be used.

Packaging

Item no: 42231802-00172 In 400g – 500g container

Containing per 100ml

	Minimum	**Maximum**	**Upper Limit**
Energy	250KJ	295kJ	
Protein	1.1g	2.1g	
Carbohydrate	5.5g	9.7g	
Fat	2.6g	4.1g	
LCT	2.57g	3.32g	
Vitamin A	38.5mcgRE		127mcgRE
Vitamin D	0.66mcg	1.77mcg	
Vitamin E	0.33mgαTE		3.54mgαTE
Vitamin K	2.75mcg		19.18mcg
Vitamin C	6.82mg		50mg
Vitamin B1	38.5mcg		212mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	52.3mcg		351mcg
Vitamin B6	23.1mcg		132mcg
Vitamin B12	0.07mcg		1.17mcg
Folic acid	6.77mcg		35.4mcg
Calcium	33mg		103mg
Iron	0.27mg		1.0mg
Sodium	13.71mg	37.17mg	
Potassium	38.5mg	114.17mg	
Zinc	0.33mg		1.06mg

Phosphorus	16.5mg		70.8mg
Magnesium	3.3mg		10.62mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML		
	Minimum	**Maximum**	**Upper Limit**
Energy	250KJ	295kJ	
Protein	1.1g	2.1g	
Carbohydrate	5.5g	9.7g	
Fat	2.6g	4.1g	
LCT	2.57g	3.32g	
Vitamin A	38.5mcgRE		127mcgRE
Vitamin D	0.66mcg	1.77mcg	
Vitamin E	0.33mgαTE		3.54mgαTE
Vitamin K	2.75mcg		19.18mcg
Vitamin C	6.82mg		50mg
Vitamin B1	38.5mcg		212mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	52.3mcg		351mcg
Vitamin B6	23.1mcg		132mcg
Vitamin B12	0.07mcg		1.17mcg
Folic acid	6.77mcg		35.4mcg
Calcium	33mg		103mg
Iron	0.27mg		1.0mg
Sodium	13.71mg	37.17mg	
Potassium	38.5mg	114.17mg	
Zinc	0.33mg		1.06mg
Phosphorus	16.5mg		70.8mg
Magnesium	3.3mg		10.62mg

Microbiological tests:

Microbiological criteria should be established in the context of risk management options and in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXC 21-97). The manufacturer is responsible to elaborate an analytical plan for the finished products mentioned above. 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* & *Enterobacter Sakazakii*. Following the sampling plan and

recommended method (or alternative validated method) as detailed in Annex I of the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008) for *Salmonella:* Method: ISO 6579 and for *Enterobacter Sakazakii*: Method: ISO/TS 22964:2006.

Table: Microbiological Criteria

Microorganisms	**N**	**C**	**m**	**Class Plan**
**Salmonella*	60	0	0/25 g	2
***Enterobacter Asakazakii*	30	0	0/10 g	2

Where

- n: number of samples that must conform to the criteria
- c: the maximum allowable number of defective sample units in a 2-class plan
- m: a microbiological limit which, in a 2-class plan, separates good quality from defective quality

*The mean concentration detected is 1 cfu in 526g (if the assumed standard deviation is 0.8 and probability of detection is 95%).
**The mean concentration detected is 1 cfu in 340g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 100g (if the assumed standard deviation is 0.5 and probability of detection is 99%)

Applicable Reference: the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008).

1.6 FOLLOW-ON FORMULA FOR INFANTS

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 probiotics may be used. L (+) Lactic acid producing cultures for the purpose of acidifying the formula may be used.

Packaging

Item no: 42231802-00177 In 100-200ml RTU Container

Item no: 42231802-00178 In 200-300ml RTU Container

Containing per 100ml

	Minimum	**Maximum**	**Upper Limit**
Energy	250kJ	355kJ	
Protein	1.35g	4.19g	
Casein Protein	>0.68g		
Carbohydrate	5.5g	15.0 g	
Fat	1.93g	4.54g	
Vitamin A	49.5mcgRE		191.7mcgRE
Vitamin D	0.69mcg	2.66 mcg	
Vitamin E	0.41 mgαTE		4.2mgαTE
Vitamin K	2.75mcg		23mcg
Vitamin C	5.23mg		61.2mg
Vitamin B1	27.5mcg		259.2mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	165mcg		351mcg
Vitamin B6	30.25mcg		162mcg
Vitamin B12	0.11mcg		1.29mcg
Folic Acid	2.75mcg		43.2mcg
Calcium	60.5mg		126mg
Iron	0.69mg	1.6 mg	
Sodium	13.75mg		68.04mg
Zinc	0.33mg		1.30mg
Phosphorus	38.5mg		86.4mg

Potassium	55mg	139.32mg	
Magnesium	3.85mg		12.96mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	**LIMIT PER 100ML**		
	Minimum	**Maximum**	**Upper Limit**
Energy	250kJ	355kJ	
Protein	1.35g	4.19g	
Casein Protein	>0.68g		
Carbohydrate	5.5g	15.0 g	
Fat	1.93g	4.54g	
Vitamin A	49.5mcgRE		191.7mcgRE
Vitamin D	0.69mcg	2.66 mcg	
Vitamin E	0.41 mgαTE		4.2mgαTE
Vitamin K	2.75mcg		23mcg
Vitamin C	5.23mg		61.2mg
Vitamin B1	27.5mcg		259.2mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	165mcg		351mcg
Vitamin B6	30.25mcg		162mcg
Vitamin B12	0.11mcg		1.29mcg
Folic Acid	2.75mcg		43.2mcg
Calcium	60.5mg		126mg
Iron	0.69mg	1.6 mg	
Sodium	13.75mg		68.04mg
Zinc	0.33mg		1.30mg
Phosphorus	38.5mg		86.4mg
Potassium	55mg	139.32mg	
Magnesium	3.85mg		12.96mg

Microbiological tests:

Microbiological criteria should be established in the context of risk management options and in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXC 21-97). The manufacturer is responsible to elaborate an analytical plan for the finished products mentioned above. 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* & *Enterobacter Sakazakii*. Following the sampling plan and recommended method (or alternative validated method) as detailed in Annex I of the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008) for *Salmonella:* Method: ISO 6579 and for *Enterobacter Sakazakii*: Method: ISO/TS 22964:2006.

Table: Microbiological Criteria

Microorganisms	**N**	**c**	**m**	**Class Plan**
**Salmonella*	60	0	0/25 g	2
***Enterobacter Asakazakii*	30	0	0/10 g	2

Where

- n: number of samples that must conform to the criteria
- c: the maximum allowable number of defective sample units in a 2-class plan
- m: a microbiological limit which, in a 2-class plan, separates good quality from defective quality

*The mean concentration detected is 1 cfu in 526g (if the assumed standard deviation is 0.8 and probability of detection is 95%).
**The mean concentration detected is 1 cfu in 340g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 100g (if the assumed standard deviation is 0.5 and probability of detection is 99%)

Applicable Reference: the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008).

1.7 INFANT FORMULA CONTAINING MCTs

Description: Low fat, protein containing feed that is high in MCTs.

Indication for Use: Feed for infants requiring MCTs.

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 probiotics may be used. L (+) Lactic acid producing cultures for the purpose of acidifying the formula may be used.

Packaging

Item no: 42231802-00181 In 400g – 500g container

Containing per 100ml

	Minimum	Maximum	Upper Limit
Energy	250KJ	355KJ	
Protein	2g	4g	
Carbohydrate	5g	15g	
Fat	2g	5g	
MCT	>1.5g		
Vitamin A	38.5mcgRE		191.7mcgRE
Vitamin D	0.66mcg	2.66mcg	
Vitamin E	0.33mgαTE		4.2mgαTE
Vitamin K	2.75mcg		23mcg
Vitamin C	6.82mg		61.2mg
Vitamin B1	38.5mcg		259.2mcg
Niacin	192mcg		1062mcg
Vitamin B2	47.5mcg		351mcg
Vitamin B6	23.1mcg		162mcg
Vitamin B12	0.06mcg		1.29mcg
Folic acid	6.77mcg		43.2mcg
Calcium	33mg		126mg
Iron	0.27mg	1.6mg	
Sodium	13.75mg		68.04mg
Potassium	38.50mg	139.32mg	
Zinc	0.33mg		1.3mg
Phosphorus	16.5mg		86.4mg
Magnesium	3.3mg		12.96mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML		
	Minimum	**Maximum**	**Upper Limit**
Energy	250KJ	355KJ	
Protein	2g	4g	
Carbohydrate	5g	15g	
Fat	2g	5g	
MCT	>1.5g		
Vitamin A	38.5mcgRE		191.7mcgRE
Vitamin D	0.66mcg	2.66mcg	
Vitamin E	0.33mgαTE		4.2mgαTE
Vitamin K	2.75mcg		23mcg
Vitamin C	6.82mg		61.2mg
Vitamin B1	38.5mcg		259.2mcg
Niacin	192mcg		1062mcg
Vitamin B2	47.5mcg		351mcg
Vitamin B6	23.1mcg		162mcg
Vitamin B12	0.06mcg		1.29mcg
Folic acid	6.77mcg		43.2mcg
Calcium	33mg		126mg
Iron	0.27mg	1.6mg	
Sodium	13.75mg		68.04mg
Potassium	38.50mg	139.32mg	
Zinc	0.33mg		1.3mg
Phosphorus	16.5mg		86.4mg
Magnesium	3.3mg		12.96mg

Microbiological tests:

Microbiological criteria should be established in the context of risk management options and in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXC 21-97). The manufacturer is responsible to elaborate an analytical plan for the finished products mentioned above. 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* & *Enterobacter Sakazakii*. Following the sampling plan and recommended method (or alternative validated method) as detailed in Annex I of the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008) for *Salmonella:* Method: ISO 6579 and for *Enterobacter Sakazakii*: Method: ISO/TS 22964:2006.

Table: Microbiological Criteria

Microorganisms	N	C	m	Class Plan
**Salmonella*	60	0	0/25 g	2
***Enterobacter Asakazakii*	30	0	0/10 g	2

Where

- n: number of samples that must conform to the criteria
- c: the maximum allowable number of defective sample units in a 2-class plan
- m: a microbiological limit which, in a 2-class plan, separates good quality from defective quality

*The mean concentration detected is 1 cfu in 526g (if the assumed standard deviation is 0.8 and probability of detection is 95%).
**The mean concentration detected is 1 cfu in 340g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 100g (if the assumed standard deviation is 0.5 and probability of detection is 99%)

Applicable Reference: the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008).

1.8 ACIDIFIED INFANT FORMULA

Description: A whey dominant acidified infant formula.

Indication for Use: For infants required 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 probiotics may be used. L (+) Lactic acid producing cultures for the purpose of acidifying the formula may be used.

Packaging

Item no: 42231802-00182 In 400g- 500g container

Containing per 100ml

	Minimum	**Maximum**	**Upper Limit**
Energy	250KJ	295kJ	
Protein	1.13g	2.1g	
Carbohydrate	5.5g	9.7g	
Fat	2.6g	4.1g	
Vitamin A	38.5mcgRE		127mcgRE
Vitamin D	0.66mcg	1.77mcg	
Vitamin E	0.33mgαTE		3.54mgαTE
Vitamin K	2.75mcg		19.18mcg
Vitamin C	6.82mg		50mg
Vitamin B1	38.5mcg		212mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	52.3mcg		351mcg
Vitamin B6	23.1mcg		132mcg
Vitamin B12	0.07mcg		1.17mcg
Folic acid	6.77mcg		35.4mcg
Calcium	33mg		103mg
Iron	0.27mg		1.0mg
Sodium	13.71mg	37.17mg	
Potassium	38.5mg	114.17mg	
Zinc	0.33mg		1.06mg
Phosphorus	16.5mg		70.8mg
Magnesium	3.3mg		10.62mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML		
	Minimum	**Maximum**	**Upper Limit**
Energy	250KJ	295kJ	
Protein	1.13g	2.1g	
Carbohydrate	5.5g	9.7g	
Fat	2.6g	4.1g	
Vitamin A	38.5mcgRE		127mcgRE
Vitamin D	0.66mcg	1.77mcg	
Vitamin E	0.33mgαTE		3.54mgαTE
Vitamin K	2.75mcg		19.18mcg
Vitamin C	6.82mg		50mg
Vitamin B1	38.5mcg		212mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	52.3mcg		351mcg
Vitamin B6	23.1mcg		132mcg
Vitamin B12	0.07mcg		1.17mcg
Folic acid	6.77mcg		35.4mcg
Calcium	33mg		103mg
Iron	0.27mg		1.0mg
Sodium	13.71mg	37.17mg	
Potassium	38.5mg	114.17mg	
Zinc	0.33mg		1.06mg
Phosphorus	16.5mg		70.8mg
Magnesium	3.3mg		10.62mg

Microbiological tests:

Microbiological criteria should be established in the context of risk management options and in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXC 21-97). The manufacturer is responsible to elaborate an analytical plan for the finished products mentioned above. 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* & *Enterobacter Sakazakii*. Following the sampling plan and recommended method (or alternative validated method) as detailed in Annex I of the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008) for *Salmonella:* Method: ISO 6579 and for *Enterobacter Sakazakii*: Method: ISO/TS 22964:2006.

Table: Microbiological Criteria

Microorganisms	N	C	m	Class Plan
**Salmonella*	60	0	0/25 g	2
***Enterobacter Asakazakii*	30	0	0/10 g	2

Where

- n: number of samples that must conform to the criteria
- c: the maximum allowable number of defective sample units in a 2-class plan
- m: a microbiological limit which, in a 2-class plan, separates good quality from defective quality

*The mean concentration detected is 1 cfu in 526g (if the assumed standard deviation is 0.8 and probability of detection is 95%).
**The mean concentration detected is 1 cfu in 340g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 100g (if the assumed standard deviation is 0.5 and probability of detection is 99%)

Applicable Reference: the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008).

1.10 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 probiotics may be used. L (+) Lactic acid producing cultures for the purpose of acidifying the formula may be used.

Packaging

Item no: 42231802-00022 In 400g- 500g container

Item no: 42231802-00187 In 50ml – 100ml RTU Container

Item no: 42231802-00189 In 250-300ml RTU Container

Containing per 100ml

	Minimum	**Maximum**	**Upper Limit**
Energy	250KJ	295KJ	
Protein	1.1g	2.1g	
Carbohydrate	5.5g	9.7g	
Fat	2.6g	4.1g	
Vitamin A	38.5mcgRE		127mcgRE
Vitamin D	0.66mcg	1.77mcg	
Vitamin E	0.33mgαTE		3.54mgαTE
Vitamin K	2.75mcg		19.18mcg
Vitamin C	6.82mg		50mg
Vitamin B1	38.5mcg		212mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	52.3mcg		351mcg
Vitamin B6	23.1mcg		132mcg
Vitamin B12	0.07mcg		1.17mcg
Folic acid	6.77mcg		35.4mcg
Calcium	33mg		103mg
Iron	0.27mg		1.0mg
Sodium	13.75mg	37.17mg	
Zinc	0.33mg		1.06mg
Phosphorus	16.5mg		70.8mg

Magnesium	3.3mg		10.62mg
Potassium	38.5mg	114.17mg	

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML		
	Minimum	**Maximum**	**Upper Limit**
Energy	250KJ	295KJ	
Protein	1.1g	2.1g	
Carbohydrate	5.5g	9.7g	
Fat	2.6g	4.1g	
Vitamin A	38.5mcgRE		127mcgRE
Vitamin D	0.66mcg	1.77mcg	
Vitamin E	0.33mgαTE		3.54mgαTE
Vitamin K	2.75mcg		19.18mcg
Vitamin C	6.82mg		50mg
Vitamin B1	38.5mcg		212mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	52.3mcg		351mcg
Vitamin B6	23.1mcg		132mcg
Vitamin B12	0.07mcg		1.17mcg
Folic acid	6.77mcg		35.4mcg
Calcium	33mg		103mg
Iron	0.27mg		1.0mg
Sodium	13.75mg	37.17mg	
Zinc	0.33mg		1.06mg
Phosphorus	16.5mg		70.8mg
Magnesium	3.3mg		10.62mg
Potassium	38.5mg	114.17mg	

Microbiological tests:

Microbiological criteria should be established in the context of risk management options and in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXC 21-97). The manufacturer is responsible to elaborate an analytical plan for the finished products mentioned above. 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* & *Enterobacter Sakazakii*. Following the sampling plan and

recommended method (or alternative validated method) as detailed in Annex I of the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008) for *Salmonella:* Method: ISO 6579 and for *Enterobacter Sakazakii*: Method: ISO/TS 22964:2006.

Table: Microbiological Criteria

Microorganisms	**N**	**C**	**m**	**Class Plan**
**Salmonella*	60	0	0/25 g	2
***Enterobacter Asakazakii*	30	0	0/10 g	2

Where

- n: number of samples that must conform to the criteria
- c: the maximum allowable number of defective sample units in a 2-class plan
- m: a microbiological limit which, in a 2-class plan, separates good quality from defective quality

*The mean concentration detected is 1 cfu in 526g (if the assumed standard deviation is 0.8 and probability of detection is 95%).
**The mean concentration detected is 1 cfu in 340g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 100g (if the assumed standard deviation is 0.5 and probability of detection is 99%)

Applicable Reference: the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008).

1.11 EXTENSIVELY HYDROLYZED FORMULA FOR INFANTS: WHEY DOMINANT WITH MCT

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

Indication for Use: Infant formula for the dietary management of allergies and /or malabsorption.

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 probiotics may be used. L (+) Lactic acid producing cultures for the purpose of acidifying the formula may be used.

Packaging

Item no: 42231802-00192 In 75ml -100ml RTU container

Item no: 42231802-00193 In 200ml-300ml RTU container

Item no: 42231802-00194 In 400g- 500g container

Containing per 100ml

	Minimum	**Maximum**	**Upper Limit**
Energy	250KJ	355KJ	
Protein	1.0g	2.0g	
Carbohydrate	5.0g	10.0g	
Fat	2.5g	6.0g	
MCT	>1g		
Vitamin A	38.5mcg RE		191.7mcg RE
Vitamin D	0.66mcg	2.66mcg	
Vitamin E	0.33mgαTE		4.2mgαTE
Vitamin K	2.75mcg		23mcg
Vitamin C	6.82mg		61.2mg
Vitamin B1	38.5mcg		259.2mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	52.3mcg		351mcg
Vitamin B6	23.1mcg		162mcg
Vitamin B12	0.07mcg		1.29mcg
Folic acid	6.77mcg		43.2mcg
Calcium	33mg		126mg
Iron	0.27mg		1.6mg
Sodium	13.75mg	68.04mg	
Zinc	0.33mg		1.3mg

Phosphorus	16.5mg		86.4mg
Magnesium	3.3mg		12.96mg
Potassium	38.5mg		139.32mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML		
	Minimum	**Maximum**	**Upper Limit**
Energy	250KJ	355KJ	
Protein	1.0g	2.0g	
Carbohydrate	5.0g	10.0g	
Fat	2.5g	6.0g	
MCT	>1g		
Vitamin A	38.5mcg RE		191.7mcg RE
Vitamin D	0.66mcg	2.66mcg	
Vitamin E	0.33mgαTE		4.2mgαTE
Vitamin K	2.75mcg		23mcg
Vitamin C	6.82mg		61.2mg
Vitamin B1	38.5mcg		259.2mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	52.3mcg		351mcg
Vitamin B6	23.1mcg		162mcg
Vitamin B12	0.07mcg		1.29mcg
Folic acid	6.77mcg		43.2mcg
Calcium	33mg		126mg
Iron	0.27mg		1.6mg
Sodium	13.75mg	68.04mg	
Zinc	0.33mg		1.3mg
Phosphorus	16.5mg		86.4mg
Magnesium	3.3mg		12.96mg
Potassium	38.5mg		139.32mg

Microbiological tests:

Microbiological criteria should be established in the context of risk management options and in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXC 21-97). The manufacturer is responsible to elaborate an analytical plan for the finished products mentioned above. 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* & *Enterobacter Sakazakii*. Following the sampling plan and recommended method (or alternative validated method) as detailed in Annex I of the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008) for *Salmonella:* Method: ISO 6579 and for *Enterobacter Sakazakii*: Method: ISO/TS 22964:2006.

Table: Microbiological Criteria

Microorganisms	**N**	**C**	**m**	**Class Plan**
**Salmonella*	60	0	0/25 g	2
***Enterobacter Asakazakii*	30	0	0/10 g	2

Where

- n: number of samples that must conform to the criteria
- c: the maximum allowable number of defective sample units in a 2-class plan
- m: a microbiological limit which, in a 2-class plan, separates good quality from defective quality

*The mean concentration detected is 1 cfu in 526g (if the assumed standard deviation is 0.8 and probability of detection is 95%).
**The mean concentration detected is 1 cfu in 340g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 100g (if the assumed standard deviation is 0.5 and probability of detection is 99%)

Applicable Reference: the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008).

1.12 HYDROLYZED PROTEIN FORMULA FOR ALLERGY: WHEY DOMINANT WITHOUT MCT

Description: Hydrolysed whey dominant 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 probiotics may be used. L (+) Lactic acid producing cultures for the purpose of acidifying the formula may be used.

Packaging

Item no: 42231802-00196 In 200ml-300ml RTU container

Item no: 42231802-00197 In 400g- 500g container

Containing per 100ml:

	Minimum	**Maximum**	**Upper Limit**
Energy	250KJ	355KJ	
Protein	1.0g	2.0g	
Carbohydrate	5.0g	10.0g	
Fat	2.5g	5.0g	
Vitamin A	38.5mcgRE		191.7mcgRE
Vitamin D	0.66mcg	2.66mcg	
Vitamin E	0.33 mgαTE		4.2mgαTE
Vitamin K	2.75mcg		23mcg
Vitamin C	6.82mg		61.2mg
Vitamin B1	38.5mcg		259.2mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	52.3mcg		351mcg
Vitamin B6	23.1mcg		162mcg
Vitamin B12	0.07mcg		1.29mcg
Folic acid	6.77mcg		43.2mcg
Calcium	33mg		126mg
Iron	0.27mg		1.60mg
Sodium	13.75mg	68.04mg	
Zinc	0.33mg		1.3mg
Phosphorus	16.5mg		86.4mg
Magnesium	3.3mg		12.96mg
Potassium	38.5mg		139.32mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML		
	Minimum	**Maximum**	**Upper Limit**
Energy	250KJ	355KJ	
Protein	1.0g	2.0g	
Carbohydrate	5.0g	10.0g	
Fat	2.5g	5.0g	
Vitamin A	38.5mcgRE		191.7mcgRE
Vitamin D	0.66mcg	2.66mcg	
Vitamin E	0.33 mgαTE		4.2mgαTE
Vitamin K	2.75mcg		23mcg
Vitamin C	6.82mg		61.2mg
Vitamin B1	38.5mcg		259.2mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	52.3mcg		351mcg
Vitamin B6	33.1mcg		162mcg
Vitamin B12	0.07mcg		1.29mcg
Folic acid	6.77mcg		43.2mcg
Calcium	33mg		126mg
Iron	0.27mg		1.60mg
Sodium	13.75mg	68.04mg	
Zinc	0.33mg		1.3mg
Phosphorus	16.5mg		86.4mg
Magnesium	3.3mg		12.96mg
Potassium	38.5mg		139.32mg

Microbiological tests:

Microbiological criteria should be established in the context of risk management options and in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXC 21-97). The manufacturer is responsible to elaborate an analytical plan for the finished products mentioned above. 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* & *Enterobacter Sakazakii*. Following the sampling plan and recommended method (or alternative validated method) as detailed in Annex I of the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008) for *Salmonella:* Method: ISO 6579 and for *Enterobacter Sakazakii*: Method: ISO/TS 22964:2006.

Table: Microbiological Criteria

Microorganisms	N	C	m	Class Plan
**Salmonella*	60	0	0/25 g	2
***Enterobacter Asakazakii*	30	0	0/10 g	2

Where

- n: number of samples that must conform to the criteria
- c: the maximum allowable number of defective sample units in a 2-class plan
- m: a microbiological limit which, in a 2-class plan, separates good quality from defective quality

*The mean concentration detected is 1 cfu in 526g (if the assumed standard deviation is 0.8 and probability of detection is 95%).
**The mean concentration detected is 1 cfu in 340g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 100g (if the assumed standard deviation is 0.5 and probability of detection is 99%)

Applicable Reference: the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008).

1.13 ANTI-REGURGITATION/ANTI-REFLUX INFANT FORMULA

Description: Formula containing pre-gelatinized carbohydrate.

Indication for Use: For infants with reflux/ 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 probiotics may be used. L (+) Lactic acid producing cultures for the purpose of acidifying the formula may be used.

Packaging

Item no: 42231802-00198 In 400g – 500g container

Item no: In 800-1000g container

Containing per 100ml:

	Minimum	Maximum	Upper Limit
Energy	250kJ	355kJ	
Protein	1.0g	2.0g	
Carbohydrate	5.0g	10g	
Fat	2.5g	5.0g	
Vitamin A	38.5mcgRE		191.7mcgRE
Vitamin D	0.66mcg	2.66mcg	
Vitamin E	0.33 mgαTE		4.2mgαTE
Vitamin K	2.75mcg		23mcg
Vitamin C	6.82mg		61.2mg
Vitamin B1	38.5mcg		259.2mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	52.3mcg		351mcg
Vitamin B6	23.1mcg		162mcg
Vitamin B12	0.07mcg		1.29mcg
Folic acid	6.77mcg		43.2mcg
Calcium	33mg		126mg
Iron	0.27mg		1.60mg
Sodium	13.75mg	68.04mg	
Zinc	0.33mg		1.3mg
Phosphorus	16.5mg		86.4mg
Magnesium	3.3mg		12.96mg
Potassium	38.5mg		139.32mg

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 further quality assessment.

List of Compulsory Tests:

PARAMETERS	LIMIT PER 100ML		
	Minimum	**Maximum**	**Upper Limit**
Energy	250kJ	355kJ	
Protein	1.0g	2.0g	
Carbohydrate	5.0g	10g	
Fat	2.5g	5.0g	
Vitamin A	38.5mcgRE		191.7mcgRE
Vitamin D	0.66mcg	2.66mcg	
Vitamin E	0.33 mgαTE		4.2mgαTE
Vitamin K	2.75mcg		23mcg
Vitamin C	6.82mg		61.2mg
Vitamin B1	38.5mcg		259.2mcg
Niacin	192.5mcg		1062mcg
Vitamin B2	52.3mcg		351mcg
Vitamin B6	23.1mcg		162mcg
Vitamin B12	0.07mcg		1.29mcg
Folic acid	6.77mcg		43.2mcg
Calcium	33mg		126mg
Iron	0.27mg		1.60mg
Sodium	13.75mg	68.04mg	
Zinc	0.33mg		1.3mg
Phosphorus	16.5mg		86.4mg
Magnesium	3.3mg		12.96mg
Potassium	38.5mg		139.32mg

Microbiological tests:

Microbiological criteria should be established in the context of risk management options and in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXC 21-97). The manufacturer is responsible to elaborate an analytical plan for the finished products mentioned above. 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* & *Enterobacter Sakazakii*. Following the sampling plan and recommended method (or alternative validated method) as detailed in Annex I of the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008) for *Salmonella:* Method: ISO 6579 and for *Enterobacter Sakazakii*: Method: ISO/TS 22964:2006.

Table: Microbiological Criteria

Microorganisms	N	C	m	Class Plan
**Salmonella*	60	0	0/25 g	2
***Enterobacter Asakazakii*	30	0	0/10 g	2

Where

- n: number of samples that must conform to the criteria
- c: the maximum allowable number of defective sample units in a 2-class plan
- m: a microbiological limit which, in a 2-class plan, separates good quality from defective quality

*The mean concentration detected is 1 cfu in 526g (if the assumed standard deviation is 0.8 and probability of detection is 95%).
**The mean concentration detected is 1 cfu in 340g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 100g (if the assumed standard deviation is 0.5 and probability of detection is 99%)

Applicable Reference: the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008).

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 probiotics may be used. L (+) Lactic acid producing cultures for the purpose of acidifying the formula may be used.

Packaging

Item no: 42231802-00039 In 400g – 500g container

Containing per 100ml

	Minimum	**Maximum**	**Upper Limit**
Energy	250KJ	355KJ	
Protein	1.5g	3.0g	
Carbohydrate	5.0g	10.0g	
Fat	3.0g	5.0g	
Vitamin A	38.5mcgRE		191.7mcgRE
Vitamin B1	38.5mcg		259.2mcg
Vitamin C	6.82mg		61.2mg
Vitamin D	0.66mcg	2.66mcg	
Calcium	33mg		126mg
Iron	0.27mg		1.6mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	**LIMIT PER 100ML**		
	Minimum	**Maximum**	**Upper Limit**
Energy	250KJ	355KJ	
Protein	1.5g	3.0g	
Carbohydrate	5.0g	10.0g	
Fat	3.0g	5.0g	
Vitamin A	38.5mcgRE		191.7mcgRE

Vitamin B1	38.5mcg		259.2mcg
Vitamin C	6.82mg		61.2mg
Vitamin D	0.66mcg	2.66mcg	
Calcium	33mg		126mg
Iron	0.27mg		1.6mg

Microbiological tests:

Microbiological criteria should be established in the context of risk management options and in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CXC 21-97). The manufacturer is responsible to elaborate an analytical plan for the finished products mentioned above. 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* & *Enterobacter Sakazakii*. Following the sampling plan and recommended method (or alternative validated method) as detailed in Annex I of the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008) for *Salmonella:* Method: ISO 6579 and for *Enterobacter Sakazakii*: Method: ISO/TS 22964:2006.

Table: Microbiological Criteria

Microorganisms	**N**	**C**	**m**	**Class Plan**
**Salmonella*	60	0	0/25 g	2
***Enterobacter Asakazakii*	30	0	0/10 g	2

Where

- n: number of samples that must conform to the criteria
- c: the maximum allowable number of defective sample units in a 2-class plan
- m: a microbiological limit which, in a 2-class plan, separates good quality from defective quality

*The mean concentration detected is 1 cfu in 526g (if the assumed standard deviation is 0.8 and probability of detection is 95%).
**The mean concentration detected is 1 cfu in 340g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 100g (if the assumed standard deviation is 0.5 and probability of detection is 99%)

Applicable Reference: the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (*CXC 66 2008).

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.

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

Packaging

Item no: 42231802-00204 In 400g - 500g container

Containing per 100ml	
Energy	420 - 450kJ
Protein	2.5-3.5g
Carbohydrate	10 – 15g
Fat	3.5 - 6.0g
Vitamin A	22-110mcg
Vitamin B1	0.1-0.5mg
Vitamin B2	0.1-0.5mg
Niacin	0.44-1.2mg
Vitamin B6	0.036-3.60mg
Folate	11-36mcg
Vitamin B12	0.07-0.5mcg
Pantothenic Acid	0.15-1.0mg
Biotin	0.59-10.0mcg
Vitamin C	1.1-72mg
Vitamin D	1.1-5.0 mcg
Vitamin E	0.44-30mg
Vitamin K	2.2-10.0mcg
Calcium	51.3-180mg
Phosphorous	33.73-120mg
Magnesium	5.86-21.33mg
Iron	0.51-2.4mg
Zinc	0.22-1.38mg
Iodine	6.6-36mcg
Selenium	1.47-16.79mcg
Copper	0.025-0.25mg
Sodium	50-80mg
Potassium	110 – 150mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML
Energy	420 - 450kJ
Protein	2.5-3.5g
Carbohydrate	10 – 15g
Fat	3.5 - 6.0g
Vitamin A	22-110mcg
Iron	0.51-2.4mg
Sodium	50-80mg
Potassium	110 – 150mg

Microbiological and chemical analyses 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

2.3 PAEDIATRIC FEED WITH FIBRE PROVIDNG 1KCAL/ML

Description: Feed with fibre providing 1kcal/ml. Gluten free and lactose free.

Indication for Use: Feed for paediatrics with additional nutritional requirements or inadequate food intake.

Packaging

Item no: 42231802-00211 In 400ml-600ml RTH container

Containing per 100ml	
Energy	420-450kJ
Protein	2.0-4.0g
Carbohydrate	10 – 15g
Fat	3.0 - 6.0g
Fibre	1-3g
Vitamin A	22-110mcg
Vitamin B1	0.1-0.5mg
Vitamin B2	0.1-0.5mg
Niacin	0.44-1.2mg
Vitamin B6	0.036-3.6mg
Folate	11-36mcg
Vitamin B12	0.07-0.5mcg
Pantothenic Acid	0.15-1.0mg
Biotin	0.59-10.0mcg
Vitamin C	1.1-72mg
Vitamin D	1.1-5.0mcg
Vitamin E	0.44-30mg
Vitamin K	2.2-10.0mcg
Calcium	51.3-180mg
Phosphorous	33.73-120mg
Magnesium	5.86-21.33mg
Iron	0.51-2.4mg
Zinc	0.22-1.38mg
Iodine	6.6-36mcg
Selenium	1.47-16.79mcg
Copper	0.025-0.25mg
Sodium	50-80mg
Potassium	110 – 150mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML
Energy	420-450g
Protein	2.0-4.0g
Carbohydrate	10-15g
Fat	3.0-6.0g
Fibre	1-3g
Vitamin A	22-110mcg
Iron	0.51-2.4mg
Sodium	50-80mg
Potassium	110 – 150mg

Microbiological and chemical analyses 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

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 no:	42231802-00224	In 400g -500g container
Item no:	42231802-00225	In 200ml – 300ml RTU container
Item no:	42231802-00226	In 400-600ml RTH container

Containing per 100ml	
Energy	420– 440kJ
Protein	2.5 – 4.0g
Carbohydrate	10– 15g
Fat	3 – 6g
MCT	1.5-3g
Vitamin A	22 – 110mcg
Vitamin B1	0.1-0.5mg
Vitamin B2	0.1-0.5mg
Niacin	0.44-1.2mg
Vitamin B6	0.036-3.6mg
Folate	11-36mcg
Vitamin B12	0.07-0.5mcg
Pantothenic Acid	0.15-1.0mg
Biotin	0.59-10.0mcg
Vitamin C	1.1-72mg
Vitamin D	1.1-5.0mcg
Vitamin E	0.44-30mg
Vitamin K	2.2-10.0mcg
Calcium	51.3-180mg
Phosphorous	33.73-120mg
Magnesium	5.86-21.33mg
Iron	0.51-2.4mg
Zinc	0.22-1.38mg
Iodine	6.6-36mcg
Selenium	1.47-16.79mcg
Copper	0.025-0.25mg
Sodium	50-80mg
Potassium	110 – 150mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML
Energy	420– 440kJ
Protein	2.5 – 4.0g
Carbohydrate	10– 15g
Fat	3 – 6g
MCT	1.5-3g
Vitamin A	22-110mcg
Iron	0.51-2.4mg
Sodium	50-80mg
Potassium	110 – 150mg

Microbiological and chemical analyses 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

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

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

Indication for Use: Feed for paediatrics with drug resistant epilepsy. Pyruvate dehydrogenase (E1) deficiency. Glucose transporter 1 deficiency syndrome.

Packaging

Item no: 42231802-00230 In 300 -400g container

Containing per 100ml	
Energy	400 – 620kJ
Protein	2.0 – 4.0g
Carbohydrate	<1.0g
Fat	10– 30g
Vitamin A	22-110mcg
Vitamin B1	0.1-0.5mg
Vitamin B2	0.1-0.5mg
Niacin	0.44-1.2mg
Vitamin B6	0.036-3.6mg
Folate	11-36mcg
Vitamin B12	0.07-0.5mcg
Pantothenic Acid	0.15-1.0mg
Biotin	0.59-10.0mcg
Vitamin C	1.1-72mg
Vitamin D	1.1-5.0mcg
Vitamin E	0.44-30mg
Vitamin K	2.2-10.0mcg
Calcium	51.3-180mg
Phosphorous	33.73-120mg
Magnesium	5.86-21.33mg
Iron	0.51-2.4mg
Zinc	0.22-1.38mg
Iodine	6.6-36mcg
Selenium	1.47-16.79mcg
Copper	0.025-0.25mg
Sodium	50-80mg
Potassium	110 – 150mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML
Energy	400 – 620kJ
Protein	2.0 – 4.0g
Carbohydrate	<1.0g
Fat	10– 30g
Vitamin A	22-110mcg RE
Iron	0.51-2.4mg
Sodium	50-80mg
Potassium	110-150mg

Microbiological and chemical analyses 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

2.8 ELEMENTAL FEED FOR PAEDIATRICS

Description: Hypoallergenic elemental feed for paediatrics.

Indication for Use: For paediatrics with cow's Milk Protein allergy, sensitivity to intact protein, gastroesophageal reflux, short bowel syndrome, protracted intractable diarrhoea.

Packaging

Item no: 42231802-00231 In 400g-500g Container

Containing per 100ml	
Energy	400-450 KJ
Protein	2.0-4.0g
Carbohydrate	10 -20g
Fat	3.0 -6.0g
Vitamin A	22-110mcg
Vitamin B1	0.1-0.5mg
Vitamin B2	0.1-0.5mg
Niacin	0.44-1.2mg
Vitamin B6	0.036-3.6mg
Folate	11-36mcg
Vitamin B12	0.07-0.5mcg
Pantothenic Acid	0.15-1.0mg
Biotin	0.59-10.0mcg
Vitamin C	1.1-72mg
Vitamin D	1.1-5.0mcg
Vitamin E	0.44-30mg
Vitamin K	2.2-10.0mcg
Calcium	51.3-180mg
Phosphorous	33.73-120mg
Magnesium	5.86-21.33mg
Iron	0.51-2.4mg
Zinc	0.22-1.38mg
Iodine	6.6-36mcg
Selenium	1.47-16.79mcg
Copper	0.025-0.25mg
Sodium	50-80mg
Potassium	110 – 150mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML
Energy	400-450 KJ
Protein	2.0-4.0g
Carbohydrate	10 -20g
Fat	3.0 -6.0g
Vitamin A	22-110mcg
Iron	0.51-2.4mg
Sodium	50-80mg
Potassium	110-150mg

Microbiological and chemical analyses 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

CATEGORY THREE: ADULT FEEDS

3.1 FEED FOR ADULTS, LACTOSE FREE PROVIDING 1KCAL/ML WITHOUT FIBRE

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

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

Packaging

Item no:	42231801-00045	In 200ml - 300 ml RTU container
Item no:	42231801-00047	In 500ml RTU container

Containing per 100ml	
Energy	420-450kJ
Protein	3 – 5g
Carbohydrate	12-20g
Fat	2 – 5g
Vitamin A	70-150mcg
Vitamin B1	0.1-0.5mg
Vitamin B2	0.1-0.5mg
Niacin	1.0-3.0mg
Vitamin B6	0.1-0.5mg
Folic Acid	20-60mcg
Vitamin B 12	0.5-1.0mcg
Pantothenic Acid	0.5-1.5mg
Biotin	2.0-6.0mcg
Vitamin C	2.5-100mg
Vitamin D	1.0-2.5mcg
Vitamin E	0.75-7.0mg TE
Vitamin K	6-10mcg
Calcium	60-125mg
Phosphorous	50-100mg
Magnesium	13-20mg
Iron	1.0-2.3mg
Zinc	1.0-.2.0mg
Iodine	8-50mcg
Selenium	3-18mcg
Copper	0.1-0.5mg
Sodium	60-90mg
Potassium	120-160mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML
Energy	420-450kJ
Protein	3 – 5g
Carbohydrate	12-20g
Fat	2 – 5g
Vitamin A	22-110mcg
Iron	1.0-2.3mg
Sodium	60-90mg
Potassium	120-160mg

Microbiological and chemical analyses 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

3.5 HIGH ENERGY HIGH PROTEIN FEED WITHOUT FIBRE

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

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

Packaging

Item no:	42231801-00064	In 200ml – 300ml container
Item no:	42231801-00065	In 500ml RTH container

Containing per 100ml	
Energy	840-900kJ
Protein	10-15g
Carbohydrate	15-30g
Fat	7-10g
Calcium	120- 250mg
Phosphorous	60-140mg
Potassium	130-200mg
Sodium	60-140mg
Magnesium	15-28mg
Iron	0.7-2.75mg
Zinc	0.7-2.3mg
Copper	0.06-0.6mg
Iodine	7.2-65mcg
Selenium	2.4-23mcg
Vitamin A	45-180mcgRE
Vitamin D	1.1-5.9mcg
Vitamin K	4.4-25mcg
Vitamin B1	0.06-0.5mg
Vitamin B2	0.06-0.5mg
Niacin	0.88-2.1mg
Vitamin B6	0.06-5.9mg
Vitamin B12	0.13-1.0mcg
Pantothenic acid	0.29-1.5mg
Biotin	1.46-10mcg
Folic acid	22-60mcg
Vitamin C	3.3-120mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML
Energy	840-900kJ
Protein	10-15g
Carbohydrate	15-30g
Fat	7-10g
Potassium	130-200mg
Sodium	60-140mg
Iron	0.7-2.75mg
Vitamin A	45-180mcgRE

Microbiological and chemical analyses 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

3.8 STANDARD SEMI-ELEMENTAL FEED

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

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

Packaging

Item no:	42231801-00075	In 200ml – 300ml RTU container
Item no:	42231801-00076	In 400g – 500g container

Containing per 100ml	
Energy	420kJ-450KJ
Protein	3.0 – 5.0g
Carbohydrate	10 –20g
Fat	1.5 – 4g
MCT	0.5-3.0g
Calcium	60-125mg
Phosphorous	50-100mg
Potassium	120-290mg
Sodium	50-140mg
Magnesium	13-30mg
Iodine	8-50mcg
Selenium	3-18mcg
Vitamin A	70-300mcgRE
Vitamin D	1.0-5.0mcg
Vitamin K	6-20mcg
Vitamin B1	0.1-0.5mg
Vitamin B2	0.1-0.5mg
Niacin	1.0-3.0mg
Vitamin B6	0.1-0.5mg
Vitamin B12	0.5-1.0mcg
Pantothenic Acid	0.5-1.5mg
Biotin	2.0-6.0mcg
Folic Acid	20-60mcg
Vitamin C	10-100mg
Iron	0.6-2.75mg
Zinc	0.7-2.3mg
Vitamin E	0.75-7.0mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML
Energy	420kJ-450KJ
Protein	3.0 – 5.0g
Carbohydrate	10 –20g
Fat	1.5 – 4g
Potassium	120-290mg
Sodium	50-140mg
Vitamin A	70-300mcgRE
Iron	0.6-2.75mg

Microbiological and chemical analyses 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

3.14 LOW PROTEIN FEED FOR PATIENTS WITH KIDNEY DISEASE

Description: High-energy, low-protein, low-electrolyte and low osmolarity feed that contains 1.5 - 2kcal/ml for patients with kidney disease.

Indication for Use: Enteral feed for patients with kidney disease on conservative treatment.

Packaging

Item no: 42231801-00091 In 300g-500g container

Containing per 100ml	
Energy	630 - 840kJ
Protein	2.5 – 5.0g
Carbohydrate	15– 25g
Fat	8 – 13g
Calcium	60-125mg
Iron	1 – 2.3mg
Phosphorous	40 – 90mg
Potassium	80 – 120mg
Sodium	60 – 80mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	**LIMIT PER 100ML**
Energy	630 - 840kJ
Protein	2.5 – 5.0g
Carbohydrate	15– 25g
Fat	8 – 13g
Calcium	60-125mg
Iron	1 – 2.3g
Phosphorous	40 – 90mg
Potassium	80 – 120mg
Sodium	60 – 80mg

Microbiological and chemical analyses 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

3.17 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 no: 42231801-00103 In 400g-500g container

Containing per 100ml	
Energy	420 – 500kJ
Protein	3 – 6g
Carbohydrate	10-15g
Fat	4-6g
MCT	1.0-2.7g
Dietary Fibre	0g
Vitamin A	70-150mgRE
Vitamin B6	0.1 – 0.5mg
Vitamin B12	0.5 –1.0mcg
Calcium	60-125mg
Iron	1-2.3mg
Zinc	1.0-2.0mg
Sodium	60-90mg
Potassium	120-160mg
Magnesium	13-20mg
Iodine	8.0-50mcg
Selenium	3.0-18mcg
Vitamin D	1.0-2.5mcg
Vitamin K	6.0-10mcg
Vitamin B1	0.1-0.5mg
Vitamin B2	0.1-0.5mg
Niacin	1.0-3.0mg
Pantothenic Acid	0.5-1.5mg
Biotin	2.0-6.0.0mcg
Folic Acid	20-60mcg
Vitamin C	2.5-100mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML
Energy	420 – 500kJ
Protein	3 – 6g
Carbohydrate	10-15g
Fat	4-6g
MCT	1.0-2.7g
Dietary Fibre	0g
Vitamin A	70-150mgRE
Iron	1-2.3mg
Sodium	60-90mg
Potassium	120-160mg

Microbiological and chemical analyses 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

3.22 FEED FOR SARCOPAENIC PATIENTS

Description: Lactose and gluten-free feed containing beta-hydroxy beta-methylbutyrate.

Indication for Use: For patients with sarcopenia.

Packaging

Item no: 42231801-00112 In 400-500g tin

Containing per 100ml	
Energy	400 – 550kJ
Protein	3– 5g
Carbohydrate	12 – 15g
Fat	3 – 5g
beta-hydroxy beta-methylbutyrate	0,5 – 1.0g
Vitamin C	2.5– 100mg
Calcium	60 –125mg
Phosphorus	50 – 100mg
Potassium	120 – 160mg
Sodium	60-90mg
Magnesium	13-20mg
Zinc	1 – 2mg
Iron	1.0-2.3mg
Vitamin A	70-150mcg
Vitamin B1	0.1-0.5mg
Vitamin B2	0.1-0.5mg
Niacin	1.0-3.0mg
Vitamin B6	0.1-0.5mg
Folic Acid	20-60mcg
Vitamin B 12	0.5-1.0mcg
Pantothenic Acid	0.5-1.5mg
Biotin	2.0-6.0mcg
Vitamin D	1.0-2.5mcg
Vitamin E	0.75-7.0mg TE
Vitamin K	6.0-10.0mcg
Iodine	8.0-50mcg
Selenium	3.0-18mcg
Copper	0.1-0.5mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML
Energy	400 – 550kJ
Protein	3– 5g
Carbohydrate	12 – 15g
Fat	3 – 5g
beta-hydroxy beta-methylbutyrate	0,5 – 1.0g
Potassium	120-160mg
Sodium	60-90mg
Iron	1.0-2.3mg
Vitamin A	70-150mcg

Microbiological and chemical analyses 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

3.23 SEMI ELEMENTAL IMMUNO-MODULATORY FEED

Description: Semi-elemental high energy hydrolysed feed containing whey based protein.

Indications for Use: For the ICU patient with higher protein and energy needs, requiring EPA and DHA and MCTs.

Packaging

Item no: 42231802-00501 In 500ml RTH container

Item no: 42231802-00502 In 200-300ml RTU container

Containing per 100ml	
Energy	600-650kJ
Protein	7-10g
Carbohydrate	10 – 15g
Fat	6-8g
MCT	3-4g
Omega 3 fatty acid	0.33-0.38g
Vitamin A	52.5-225mcg
Vitamin B1	0.07-0.37mg
Vitamin B2	0.07-0.37mg
Niacin	0.75-2.25mg
Vitamin B6	0.07-0.37mg
Folic Acid	15-45mcg
Vitamin B12	0.37-0.75mcg
Pantothenic Acid	0.38-1.12mg
Biotin	1.5-4.5mcg
Vitamin C	7.5-75mg
Vitamin D	0.75-3.75mcg
Vitamin E	0.75-7.0mg
Vitamin K	4.5-15mcg
Calcium	45-93mg
Phosphorous	39-75mg
Magnesium	9.75-22.5mg
Iron	0.6-2.75mg
Zinc	0.7-2.3mg
Iodine	6.0-40mcg
Selenium	2.25-13.5mcg
Sodium	37.5-105mg
Potassium	90-217mg

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 further quality assessment.

List of Compulsory Tests

Energy	600-650kJ
Protein	7-10g
Carbohydrate	10 – 15g
Fat	6-8g
MCT	3-4g
Omega 3 fatty acid	0.33-0.38g
Vitamin A	52.5-225mcgRE
Iron	0.6-2.75mg
Sodium	37.5-105mg
Potassium	90-217mg

Microbiological and chemical analyses 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

3.27 VERY RESTRICTED CALORIE FOR BARIATRIC PATIENTS

Description: Calorie restricted feed, high protein, low carbohydrate and low-fat feed.

Indication for Use: To be used as part of nutritional management of pre and post bariatric surgery patients.

Note: Product must meet the codex standard for a feed for special medical purposes.

Packaging

Item Number: 42231802-00404 50-60g powder sachet

Item Number: 42231802-00405 300-500g container

Containing per 100ml

Energy	300-400kJ
Protein	7-10g
Carbohydrate	5-10g
Fat	<3g
Fibre	<3g
Phosphorous	50-100mg
Potassium	120-160mg
Sodium	60-90mg
Vitamin A	70-150mcgRE
Vitamin D	1-2.5mcg
Vitamin E	0.75-7.0mg
Vitamin K	6.0-10mcg
Vitamin B1	0.1-0.5mg
Vitamin B2	0.1-0.5mg
Niacin	1.0-3.0mg
Vitamin B6	0.1-0.5mg
Folic Acid	20-60mcg
Vitamin B12	0.5-1.0mcg
Vitamin C	2.5-100mg
Calcium	60-125mg
Magnesium	13-20mg
Iron	1-2.3mg
Zinc	1.0-2.0mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML
Energy	300-400kJ
Protein	7-10g
Carbohydrate	5-10g
Fat	<3g
Potassium	120-160mg
Sodium	60-90mg
Vitamin A	70-150mcgRE
Iron	1-2.3mg

Microbiological and chemical analyses 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

CATEGORY FOUR: MODULAR FEEDS

4.3 CASEIN BASED PROTEIN SUPPLEMENT

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

Indication for Use: For patients with increased protein needs.

Packaging

Item no: 42231801-00116 In 200g – 300g container

Containing per 100g

Energy	1500 – 2000kJ
Protein	85-100g
Carbohydrate	<5g
Fat	<2g
Calcium	Does not exceed 1600mg
Sodium	Does not exceed 100mg
Potassium	Does not exceed 150mg
Phosphorous	Does not exceed 800mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100G
Energy	1500 – 2000kJ
Protein	85-100g
Carbohydrate	<5g
Fat	<2g
Calcium	Does not exceed 1600mg
Sodium	Does not exceed 100mg
Potassium	Does not exceed 150mg
Phosphorous	Does not exceed 800mg

Microbiological and chemical analyses 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

4.5 L-GLUTAMINE SUPPLEMENT

Description: L-glutamine.

Indication for Use: In patients receiving oral nutrition or tube feeding for gastrointestinal support.

Packaging

Item no: 42231801-00118 In 10-20g sachet

Containing per sachet:

Energy	<400KJ
Carbohydrate	<8g
L-glutamine	10g

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 further quality assessment.

List of Compulsory Tests

Energy	<400KJ
L-glutamine	10g

Microbiological and chemical analyses 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

4.6 FAT BASED ORAL SUPPLEMENT

Description: Fat emulsion with long and medium chain triglycerides providing not less than <5Kcal/ml. Should not contain protein or micronutrients. MUFA: PUFA should be 2:01.

Indication for Use: Patients who are unable to meet energy requirements.

Packaging

Item no: 42231801-00120 In 100-150ml Container

Containing per 100ml:

Energy	2100-2300 kJ
Protein	0g
Carbohydrate	<5g
Fat	50-60g

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100ML
Energy	2100-2300kJ
Protein	0g
Carbohydrate	<5g
Fat	50-60g

Microbiological and chemical analyses 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

4.7 WHEY DOMINANT PROTEIN SUPPLEMENT

Description: Whey isolate protein supplement easily dissolvable in fluids and unflavoured.

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

Packaging

Item number: 42231802-00407 In 200-300g container

Containing per 100g:

Energy	1500-2000KJ
Protein	70-100g
Carbohydrate	<20g
Fat	<5g
Calcium	Does not exceed 1600mg
Sodium	Does not exceed 500mg
Potassium	Does not exceed 800mg
Phosphorous	Does not exceed 1000mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER 100G
Energy	1500-2000KJ
Protein	70-100g
Carbohydrate	<20g
Fat	<5g
Sodium	Does not exceed 500mg
Potassium	Does not exceed 800mg
Phosphorous	Does not exceed 1000mg
Calcium	Does not exceed 1600mg

Microbiological and chemical analyses 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

CATEGORY FIVE: OTHER FEEDING PRODUCTS

5.3 FIBRE SUPPLEMENT

Description: An insoluble fibre nutritional supplement. Lactose and Gluten free.

Indication for Use: For patients requiring additional fibre as part of their diet.

Packaging

Item number: 42231802-00408 100g-300g container

Containing per sachet (<10g):

Fibre	3.5-5.0g
Fat	0g
Carbohydrate	<5g

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER SACHET
Fibre	3.5-5.0g
Fat	0g
Carbohydrate	<5g

Microbiological and chemical analyses 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

CATEGORY SIX: NUTRITION PRODUCTS FOR THE MANANGEMENT 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:	42231802-00409	In 300g-500g container
Item no:	42231802-00213	In 100ml-150ml RTU container
Item no:	42231802-00214	In 200ml-250 ml RTU container
Item no:	42231802-00215	In 400ml-600ml RTU container
Item no:	42231802-00216	In 1000ml RTU container

Quality and Safety

General quality milk based white or pale yellowish fine powder or 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)
- vitamin 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 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 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 be 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
w-3 fatty acids	0.3 – 2.5% total energy		
w-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	
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	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 further 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		<0.3
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 no:	42231802-00410	In 300-500g
Item no:	42231802-00217	In 100-150 ml RTU container
Item no:	42231802-00219	In 400-600ml RTU container
Item no:	42231802-00220	In 1000ml RTU container

T**ECHNICAL SPECIFICATIO**NS

Quality and Safety

Milk based white or pale yellowish fine powder or 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 Starting 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 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-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 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 F100 set in below shall not be 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
w-3 fatty acids	0.3 – 2.5% total energy		
w-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, 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 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-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 further 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		0.3
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.

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 are or have to be 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 no: 42231802-00200 In 50g sachets

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 the 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 extract at GMP level
    - Ethyl vanillin and vanillin: 7 mg/100 g RTU

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, 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).

[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).

[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.

Table 1: Nutritional Composition per 100g

Nutrients and nutritional values per 100g finished product	Unit	Minimum	Maximum
Energy	**kJ**	**400**	**1600**
Protein	**g**	**4.5**	**14**
Fat	**g**	**4**	**13**
Carbohydrate	**g**	**15**	**50**
Sodium	**mg**	**100**	**390**
Calcium	**mg**	**100**	**320**
Vitamin A	**mcg RE**	**70**	**150**
Vitamin D	**mcg**	**1.25**	**12**
Vitamin B1	**mcg**	**60**	**200**
Iron	**mg**	**1.2**	**8.0**
Dietary Fibre	**g**		**<5g**

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 further quality assessment.

List of Compulsory Tests

Tests	Limit per 100g	Reference method
Energy	400-1600KJ	
Protein	4.5-14g	AOAC 981.10
Fat	4-13g	AOAC 954.02
Crude fibre	<5g	AOAC 962.09
Vitamin A	70-150mcgRE	AOAC 992.04
Iron	1.2-8.0mg	AOAC 944.02
Calcium	100-320mg	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).

CATEGORY EIGHT: MICRONUTRIENTS

8.2 MICRONUTRIENTS FOR PREGNANT WOMEN

Description: The supplement for pregnant women should comply with the relevant Codex guidelines for vitamin and mineral supplements. All supplements should carry a phrase to the effect that an individual consuming vitamin and mineral supplements should inform his/her medical practitioner of taking such supplements preferably under medical supervision.

Indication for Use: Supplement for women during pregnancy and lactation.

Packaging

Item no: 42231801-00151 60 capsule in container

Containing per capsule	
Vitamin A	750-800mcgRE
Vitamin D	5-10mcg
Vitamin E	10-15mg
Vitamin C	60-85mg
Vitamin B1	1.1-1.4mg
Vitamin B2	1.1-1.4mg
Vitamin B6	1.3-1.9mcg
Vitamin B12	2.4-2.6mcg
Folic Acid	400-600mcg
Iron	24-27mg
Zinc	10-15mg
Selenium	50-65mcg
Iodine	150-220mcg
Niacin	15-18mg
Copper	1.0-1.3mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER CAPSULE
Vitamin A	750-800mcgRE
Vitamin D	5-10mcg
Vitamin E	10-15mg
Vitamin C	60-85mg
Vitamin B1	1.1-1.4mg
Vitamin B2	1.1-1.4mg
Vitamin B6	1.3-1.9mcg
Vitamin B12	2.4-2.6mcg
Folic Acid	400-600mcg
Iron	24-27mg
Zinc	10-15mg
Selenium	50-65mcg
Iodine	150-220mcg
Niacin	15-18mg
Copper	1.0-1.3mg

Microbial Analyses

PARAMETERS	LIMIT PER 1G SACHET	REFERENCE METHOD
Total CFU	max 10^3/g	AOAC 972.26
Yeast/moulds	max 10^2/g	EN 15891:2010
Salmonella sp	negative in 50 g	AACC 42-25B
Escherichia Coli	negative in 10 g	AOAC 991.14
Staphylococcus aureus	negative in 10 g	AACC 42-30B

8.3 MICRONUTRIENTS FOR ADULTS

Description: The supplement for adults should comply with the Codex guidelines for vitamin and mineral supplements (CAC/GL 55-2005), Advisory lists of Mineral salts and vitamin compounds for use for infants and children (CAC/GL 10) and other related local guidelines. All supplements should carry a phrase to the effect that an individual consuming vitamin and mineral supplements should inform his/her medical practitioner of taking such supplements preferably under medical supervision.

Indication for Use: Micronutrient Supplement for adults at risk of micronutrient deficiency.

Packaging

Item no: 42231801-00130 60 capsules in container

Containing per capsule

Vitamin A	600-900mcgRE
Vitamin D	5-10mcg
Vitamin E	10-15mg
Vitamin C	45-90mg
Vitamin B1	0.9-1.2mg
Vitamin B2	0.9-1.2mg
Vitamin B6	1.0-1.7mcg
Vitamin B12	1.8-2.4mcg
Folic Acid	400-600mcg
Iron	8-18mg
Zinc	8.0-11mg
Selenium	40-55mcg
Iodine	120-150mcg
Niacin	12-16mg
Copper	0.7-0.9mg

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 further quality assessment.

List of Compulsory Tests

PARAMETERS	LIMIT PER CAPSULE
Vitamin A	600-900mcgRE
Vitamin D	5-10mcg
Vitamin E	10-15mg
Vitamin C	45-90mg
Vitamin B1	0.9-1.2mg
Vitamin B2	0.9-1.2mg
Vitamin B6	1.0-1.7mcg

Vitamin B12	1.8-2.4mcg
Folic Acid	400-600mcg
Iron	8-18mg
Zinc	8.0-11mg
Selenium	40-55mcg
Iodine	120-150mcg
Niacin	12-16mg
Copper	0.7-0.9mg

Microbial Analyses

PARAMETERS	LIMIT PER 1G SACHET	REFERENCE METHOD
Total CFU	max 10^3/g	AOAC 972.26
Yeast/moulds	max 10^2/g	EN 15891:2010
Salmonella sp	negative in 50 g	AACC 42-25B
Escherichia Coli	negative in 10 g	AOAC 991.14
Staphylococcus aureus	negative in 10 g	AACC 42-30B

8.4 PROBIOTIC SUPPLEMENT

Description: Probiotics should improve the microbial balance in the human intestines and the functioning of the digestive tract Probiotics may contain one or more live strains and should comply with the Medicines and Related Substances Act, 1965 (ACT 101 OF 1965). The viable count of probiotic bacteria should be $1x10^9$ per single dosage unit.

Indication for Use: For the management of gastrointestinal disturbances.

Packaging

Item no:	42231801-00134	In 60 tablets (chewable, sugar-free form)
Item no:	42231801-00133	In 60 capsules
Item no:	42231801-00138	10ml

Containing per tablet/capsule

At least one or more strains of:

Lactobacillus and or Bifidobacterium as per the Medicines and Related Substances Act, 1965 (ACT 101 OF 1965). The viable count of the probiotic bacteria should be 1x 10^9CFU per single dose

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 further quality assessment.

<u>List of Compulsory Tests</u>

Limit containing per capsule/tablet

At least one or more strains of:

Lactobacillus and or Bifidobacterium as per the Medicines and Related Substances Act, 1965 (ACT 101 OF 1965). The viable count of the probiotic bacteria should be 1x 10^9CFU per single dose