USAID COMMODITY SPECIFICATION

HEB

HIGH ENERGY BISCUITS

FOR USE IN INTERNATIONAL FOOD ASSISTANCE PROGRAMS

Proposed Effective Date: March 3, 2016

USDA COMMODITY REQUIREMENTS

HEB1
HIGH ENERGY BISCUITS

FOR USE IN INTERNATIONAL FOOD ASSISTANCE PROGRAMS

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Part I COMMODITY SPECIFICATIONS

Section 1.1 Commodities

A. Product Purpose and Type

High Energy Biscuits (HEB) are designed to be high in protein and supplemented with a premix of vitamins and minerals. They are intended for general food distribution and school feeding.

USAID High Energy Biscuits shall comply, except when specified otherwise in solicitations and contracts, with the following guidelines or standards:

a) US Food and Drug Administration (FDA) Food Safety Modernization Act
b) The 21 CFR 170.3 and 21 CFR 170.30 regulations on food ingredients and additives in regard to being Generally Recognize as Safe (GRAS).
c) Guidelines on Formulated Supplementary Foods for Older Infants and Young Children, CAC/GL 08-1991 of the Codex Alimentarius.
d) Code of Hygienic Practice for Foods for Infants and Children CAC/RCP 66 - 2008 of the Codex Alimentarius;
e) Recommended International Code of Practice: General Principles of Food Hygiene CAC/RCP 1-1969 Rev 4 - 2003 including Annex "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its application".
f) General principles for addition of essential nutrients to foods: CAC/GL 09-1987 (amended 1989, 1991), of the Codex Alimentarius[1]

B. Main Ingredients

HEB must be manufactured from fresh and good quality ingredients. The product shall be free from foreign materials, substances hazardous to health, excessive moisture, insect damage and fungal contamination and must comply with all relevant national food laws and standards. HEB shall be prepared and packaged in accordance with good commercial practice (CFR - Code of Federal Regulations Title 21) and shall comply with the following U.S. Standards of Identity:

a) **Wheat flour** must conform to U.S. 21 CFR 137.105 and Codex STAN 152-1985. OR
b) **Potato flour** must conform to appropriate U.S. CFR regulation as well as any applicable international standard.
c) **Sugar** must conform to U.S. 21CFR184.1854 and Codex STAN 212-1999.
d) **Shortening** must be prepared from oil as defined by the Food and Drug Administration in 21 CFR 101.62 and in conformance with Codex STAN 210-1999, must be free from trans fatty acids and must contain only antioxidants that comply with Codex and relevant regulations.
e) **Skimmed milk** powder must conform to FDA Regulation as established in 21CFR131.110 and in conformance with Codex STAN 207-1999.
    i. It must be accompanied by a 'melamine-free' certificate.

ii. Maximum level aflatoxin M1: < 0.5 mcg/kg milk (recommended methods ISO 14501/IDF 171:2007[1] or ISO 14674/IDF 190:2005[2]).

Other raw materials and **additives** (if used) must comply with FDA Guidelines, Codex or relevant regulations. Raw materials must be stored under dry, ventilated and hygienic conditions. Only safe insecticides (i.e. phosphine) may be used for fumigation control. Where needed, fumigation must be performed by certified operators.

C. Vitamins and Minerals

Complete micronutrient premix must be purchased from an ISO 17025-approved supplier, as well as a GAIN-approved Premix Facility or any of the GAIN approved suppliers. A complete list is available at the following link: http://gpf.gainhealth.org/suppliers/current-suppliers

Micronutrient premix must be delivered to the processor of **HEB** with a complete Certificate of Analysis. The two documents must be presented with other documents to USDA for payment. Micronutrient premix must be stored in a dry, cool and clean place.

D. Process Description

a. **Formula.** Formulation shall be based on supplier experience and must include dry skimmed milk (Minimum of 4.0 g/100g of HEB) and Sugar (10.0-19.0 g/100g of HEB).

b. **Homogeneity of micronutrients.** Theoretical calculations indicate that a mixing system with a Coefficient of Variation of 10% using iron as the indicator element will enable product to meet the above variation target on 95%, provided that all conditions of mixing are rigorously applied. To conduct these calculations, see WFP handbook: Fortified Blended Food-Good Manufacturing Practice and HACCP Principles and fortification guide on http://foodqualityandsafety.wfp.org/coefficient-of-variation-calculator.

c. **Food safety and risk assessment at manufacturing premises.** For compliance with FDA Guidelines and Codex standards, the processor must be able to demonstrate by principle and practice the adoption, implementation and recording of Good Manufacturing Practice (GMP), Hazard Analysis Critical Control Point program (HACCP), Pathogen and Environmental Monitoring (PEM), zoning demarcation and a complete quality and food system program. Accordingly, USDA, USAID and/or WFP Inspector / Quality Surveyor are entitled to visit the factory without prior notice

[1] Milk and milk powder: determination of aflatoxin M1 content, clean up by immunoaffinity chromatography and determination by HPLC.
[2] Milk and milk powder: determination of aflatoxin M1 content, clean up by immunoaffinity chromatography and determination by Thin Layer Chromatography.

during any period when product is being manufactured to check that the above food safety and quality are in place, validated and being implemented.

d. **First Production Approval and subsequent audits.** HEB Suppliers are expected to go through a preparatory or first production run during which baseline data on composition, microbiology, operator training, and grading table (sensory analysis) are developed, as well as all calibrations necessary before running at full capacity. During start-up run, the supplier must run all the required analyticals in this document and ensure that the facility is capable of producing the product with the highest quality. During this phase, the contracting agency (any or multiple representatives of USDA/FGIS, USAID, and/or WFP) may choose to be present.

E. Analytical Requirements

a. Table 1 General Requirements (Based on 100g of Finished Product)[3]

No.	Component	Target
1	Moisture content	4.5% max
2	Energy	462 kcal (Min)
3	Protein	10 g min
4	Total Fat Saturated Trans fat	12 g min 5.7g max 1.34 max
5	Added Sugar	10-19 g
6	Crude Fiber	2.3 g max
7	Total Ash	3.5 g max
8	Peroxide Value	10 meq/ kg fat, max

b. Finished Product Characteristics

Organoleptic: HEB must have a typical color, pleasant smell and palatable taste which consumers will like and enjoy.

Broken: percentage of broken HEB must not be more than 5.0 percent (by weight).

Weight: one piece of HEB should weigh between 5 g and 10g.

c. Micronutrients.

HEB must be fortified to provide the following target micronutrients supplement per 100g of finished product (Table 2)

[3] These values shall be used for labeling purpose. Suppliers are encouraged to do accelerated shelf life studies to ensure these levels of micronutrients are achieved at consumption time

d. Contaminants

Table 2. Recommended micronutrient rates and chemical forms per 100g finished product[4]

No.	Vitamin/Mineral	Unit	Target[5] Levels	Chemical Forms
1	Vitamin A (Retinol)	µg	250	Palmitate 250 CWS
2	Vitamin B1	mg	0.5	Thiamine mononitrate
3	Vitamin B2	mg	0.7	Riboflavin
4	Niacin	mg	6	Nicotinamide
5	Panthothenic Acid	mg	3	Calcium d-pantothenate
6	Vitamin B6	mg	1	Pyridoxine hydrochloride
7	Folic Acid	µg	80	Folic acid
8	Vitamin B12	µg	2	Vitamin B12 – 1% in manitol
9	Vitamin C	mg	20	Ascorbic acid coated
10	Vitamin D	µg	1.9	Vit D3 100 CWS
11	Vitamin E	mg	5	Vit E 50 CWS
12	Calcium	mg	250	Calcium carbonate
13	Magnesium	mg	150	Magnesium oxide
14	Iron	mg	11	Ferrous fumarate
15	Iodine	µg	75	Potassium iodate
16	Sodium	mg	0.24	Sodium Chloride, Sodium Phosphate

Table 3. Most common contaminants and thresholds

Heavy Metals	Permissible Thresholds[6] (mg/kg body)	Per 1000 Kcal[7] (mg)	Analytical Method
Cadmium	0.050	0.12	AOAC 982.23;945.58;973.34
Arsenic	0.107	0.25	AOAC 986.15 AOAC 942.17
Lead	0.179	0.43	AOAC 972.25; 982.23
Mercury	0.036	0.09	AOAC 971.21;952.14
Tin	100.0	238	AOAC 980.19; EN 15764

[4] This table shall be used for labeling purpose. Suppliers are encouraged to do accelerated shelf life studies to ensure these levels of micronutrients are achieved at consumption time.
[5] In order to make appropriate formulations, suppliers are encouraged to understand intrinsic contributions of raw material to micronutrients as it is will influence the amount of micronutrients in finished product.
[6] Limits are calculated from the protocols and tolerable weekly intake (PTWI) in mg/kg body as defined in the CODEX STAN 193-1995: Codex General Standard for Contaminants and Toxins in Food and Feed. Calculations were done assuming as reference a 5-kg child. Equivalent and validated methods are allowed.
[7] Calculation based on PTWI, assuming a lower-end weight of 5kg average child and a 2100 calories daily requirement, using the formula: ((mg/kg-body x 5kg)/2100 kcal) x1000 kcal

Heavy Metals	Permissible Thresholds[6] (mg/kg body)	Per 1000 Kcal[7] (mg)	Analytical Method
Other Contaminants			
Contaminants	**Requirements**		**Reference method** *(*or equivalent)
Melamine/Cyanuric acid (ppb)	Max. 2.5mg/kg		http://www.who.int/foodsafety/fs_management/Melamine_methods.pdf
Aflatoxin B1, B2, G1 and G2. (ppb)	< 0.5 ppb		AACC 45-16

e. Compulsory Testing and Methods

Table 4*:* List of compulsory tests and reference methods

No	Tests	Requirements	Reference method *(or equivalent)*
1	Moisture content	Max. 4.5 %	AOAC 925.10, 2002
2	Organoleptic characteristic (color, smell and taste)	Typical color, Pleasant smell and palatable taste.	Sensorial inspection
3	Broken biscuits	Max. 5.0 % broken (by weight)	Visual inspection
4	Protein	Min. 10 g/100g	AOAC 981.10
5	Fat	Min. 12.0 g/100g	AOAC 963.15, 2000
6	Sugar (total)	10.0-19.0 g/100g	AOAC 920.189
7	Crude fiber	Max. 2.3 g/100g	AOAC 962.09
8	Ash (total)	Max. 3.5 g/100g	AOAC 942.05, ISO 2171.2000
9	Aflatoxin M1	< 0.5 ppb	AACC 45-16
10	Peroxide value	Max. 10 meq/kg fat	AOAC 965.33
11	Vitamin A-Retinol	Min. 250 mcg/100g	AOAC 960.45
12	Iron	Min. 11 mg/100g	AOAC 945.40
13	Mesophillic aerobic bacteria	< 10,000 cfu/g	ICC No 125 AACC 42-11
14	Coliforms	< 10 cfu/g	AOAC 2005.03
15	Escherichia coli	Absent in 1g	AOAC 991.14

16	Salmonella	Absent in 25g	AACC 42-25B
17	Staphylococcus aureus	< 10 cfu/g	AACC 42-30B
18	Bacillus cereus	< 10 cfu/g	AOAC 980.31
19	Yeasts and molds	< 100 cfu/g	ICC No 146
20	GMO (only if required)	Negative (< 0.9% of GMO material)	

Section 1.2 Quality Assurance

Table 5. **General guidelines for food safety and quality control**

No.	Activity	Annotations
1	**Qualification audit/ preliminary Survey**	1. A preliminary USG audit, before granting contract to potential suppliers 1. Audit must be HACCP-based 2. Written manifestation from the suppliers indicating commitment to comply with highest levels quality, proving all their written quality programs 3. Third party audits to be requested from potential suppliers, if sharable
2	**Start-up process**	1. Process capability validation 2. Generation of baseline data (production, environmental, finished product compliance) 3. Validation of sampling plans for continuous monitoring by USG
3	**Ongoing monitoring through indicative parameters**	1. Suppliers need to provide COAs 2. USG will continue to test indicative parameters both for microbiology and composition
4	**Spot, unannounced audits**	1. According to supplier production capability, hopefully measured as a function of cPk (process variability), at least annual audits will take place 2. If it is a new contract, presence will be compulsory at least for one production cycle

A. The contractor shall perform the product testing and quality analysis to ensure that the product meets the commodity specifications. The results shall be evidenced by a Certificate of Analysis (COA). Copies of the original COA must be submitted as part of the invoice package. The COA shall provide results of all tests specified.

B. Contractors shall notify the Government immediately of lots that fail to meet contract requirements.

C. **Quality Discounts**

If the product to be delivered by the contractor does not meet the quality specifications required herein, but falls within the discounts listed, the product may be delivered to the Government, but the purchase price will be reduced in accordance with the following schedule of discounts for each 100 pounds of commodity delivered. A commodity that deviates from the specifications may be rejected.

High Energy Biscuit Discounts			
Excess Moisture		**Excess Sugar**	
4.51% - 5.00%	$0.10	19.10 - 20.00 g/100g	$0.10
5.01% - 5.50%	$0.20	20.10 - 21.00 g/100g	$0.20
5.51% - 6.00%	$0.35	21.10 - 22.00 g/100g	$0.35
Deficient Protein		**Excess Crude Fiber**	
9.99 - 9.50 g/100g	$0.10	2.31 - 2.50 g/100g	$0.10
9.49 - 9.00 g/100g	$0.20	2.51 - 2.70 g/100g	$0.20
8.99 - 8.50 g/100g	$0.35	2.71 - 2.90 g/100g	$0.35
Deficient Fat		**Excess Ash**	
11.99 - 11.50 g/100g	$0.10	3.51 - 3.75 g/100g	$0.10
11.49 - 11.00 g/100g	$0.20	3.76 - 4.00 g/100g	$0.20
10.99 - 10.5 g/100g	$0.35	4.01 - 4.25 g/100g	$0.35
Deficient Iron			
10.99 - 10.50 mg/100g	$0.10		
10.49 - 10.00 mg/100g	$0.20		
9.99 - 9.50 mg/100g	$0.35		

Part 2 CONTAINER AND PACKAGING REQUIREMENTS

Section 2.1 Primary Package

It is under supplier responsibility to select a packaging material that will protect biscuits from moisture as well as vitamins and fat degradation during shelf life.

- It must be based on supplier experience and comply with relevant regulations.
- It must be food grade, have good sealing properties and be printed as per requirement.

- It must include a metalized layer to reduce permeability to Oxygen and Vapor.
- It must be stored under dry, ventilated and hygienic conditions.

Typically a laminated composed of BOPP + VMCPP (20 and 25 microns respectively) or equivalent or stronger can be used. Each package must contain 100 grams biscuits.

Section 2.2 Secondary Package

Individual packages must be stuffed in strong cardboard cartons suitable for multiple handling and must contain 10kg net biscuits. About 15-20 bags of silica gel of at least 1g each should be placed in each container in order to absorb moisture. In addition, craft paper should be laid to all sides of the container.

If the contractor purchases packaging and container ingredients from a foreign country and/or the package and container is manufactured in a foreign country, the package and container SHALL NOT display country of origin labeling. Phrases similar, but not limited to "Made in [Name of Foreign Country]" or "Product of [Name of Foreign Country]" are strictly prohibited.

Section 2.3 Labeling Requirements

Primary Packaging

- Name of the product
- USAID Logo
- Ingredient list
- Net weight
- Table 1 and Table 2
- Contract Number
- Date of manufacture
- Best used by date
- Storage instructions
- Additional markings as per contractual agreement.

Secondary Packaging

- Name of the product
- USAID Logo
- Contract Number
- Additional markings as per contractual agreement.

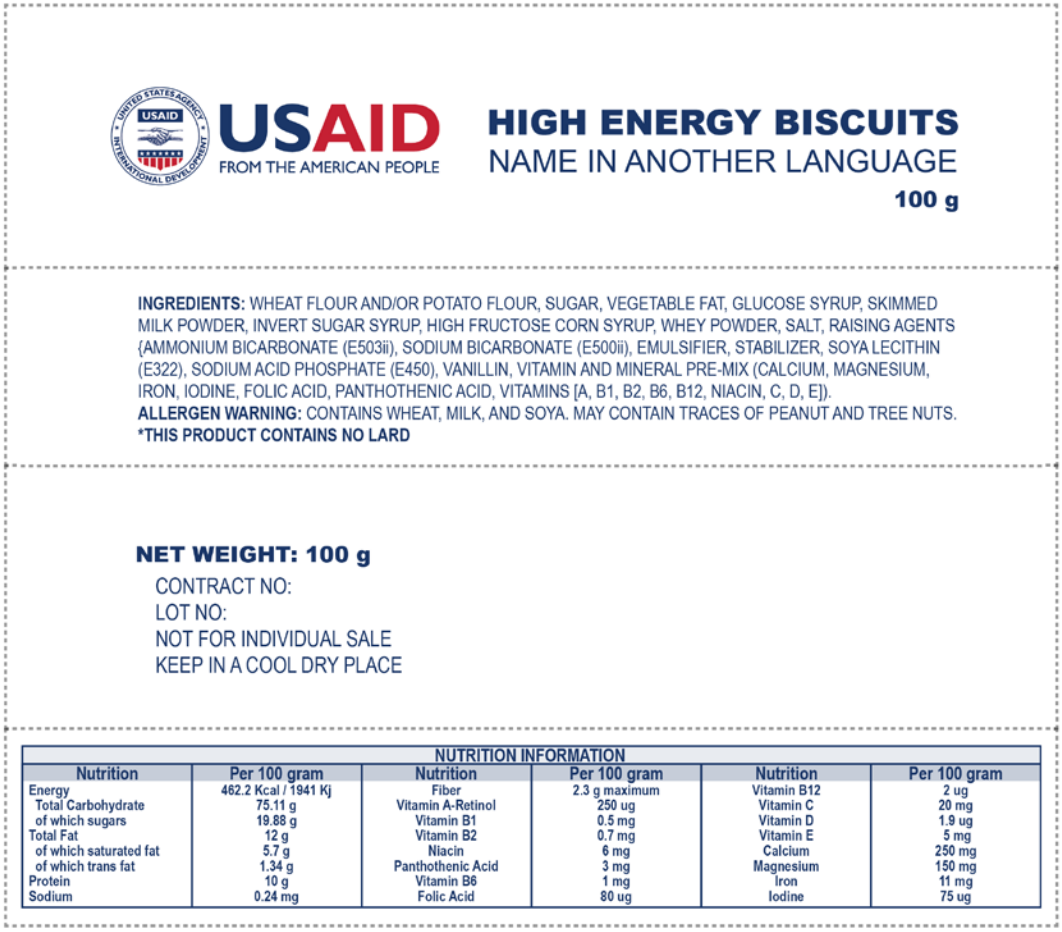
Section 2.4 Shelf Life, Shipping, and Storage

The product shall have a shelf life of 24 months at 30°C, and it shall retain all commodity specification qualities included in this specification document for at least 18 months from date

of manufacture when stored dry at ambient temperatures prevalent in the country of destination. HEB must be stored under dry, ventilated and hygienic conditions.

Exhibit A - Markings

- Primary Markings



USAID
FROM THE AMERICAN PEOPLE

HIGH ENERGY BISCUITS
NAME IN ANOTHER LANGUAGE
100 g

INGREDIENTS: WHEAT FLOUR AND/OR POTATO FLOUR, SUGAR, VEGETABLE FAT, GLUCOSE SYRUP, SKIMMED MILK POWDER, INVERT SUGAR SYRUP, HIGH FRUCTOSE CORN SYRUP, WHEY POWDER, SALT, RAISING AGENTS (AMMONIUM BICARBONATE (E503ii), SODIUM BICARBONATE (E500ii), EMULSIFIER, STABILIZER, SOYA LECITHIN (E322), SODIUM ACID PHOSPHATE (E450), VANILLIN, VITAMIN AND MINERAL PRE-MIX (CALCIUM, MAGNESIUM, IRON, IODINE, FOLIC ACID, PANTHOTHENIC ACID, VITAMINS [A, B1, B2, B6, B12, NIACIN, C, D, E]).
ALLERGEN WARNING: CONTAINS WHEAT, MILK, AND SOYA. MAY CONTAIN TRACES OF PEANUT AND TREE NUTS.
***THIS PRODUCT CONTAINS NO LARD**

NET WEIGHT: 100 g
CONTRACT NO:
LOT NO:
NOT FOR INDIVIDUAL SALE
KEEP IN A COOL DRY PLACE

NUTRITION INFORMATION

Nutrition	Per 100 gram	Nutrition	Per 100 gram	Nutrition	Per 100 gram
Energy	462.2 Kcal / 1941 Kj	Fiber	2.3 g maximum	Vitamin B12	2 ug
Total Carbohydrate	75.11 g	Vitamin A-Retinol	250 ug	Vitamin C	20 mg
of which sugars	19.88 g	Vitamin B1	0.5 mg	Vitamin D	1.9 ug
Total Fat	12 g	Vitamin B2	0.7 mg	Vitamin E	5 mg
of which saturated fat	5.7 g	Niacin	6 mg	Calcium	250 mg
of which trans fat	1.34 g	Panthothenic Acid	3 mg	Magnesium	150 mg
Protein	10 g	Vitamin B6	1 mg	Iron	11 mg
Sodium	0.24 mg	Folic Acid	80 ug	Iodine	75 ug

- Secondary Box Markings

HIGH ENERGY BISCUITS
STORE IN A DRY PLACE, PREFERABLY
SHIELDED FROM DIRECT SUNLIGHT

PRODUCT OF USA

NET WEIGHT:

CONTRACT NO:
DATE OF MANUFACTURE:
BEST USED BY:
LOT NO:

USAID
FROM THE AMERICAN PEOPLE

HIGH ENERGY BISCUITS
NAME IN ANOTHER LANGUAGE

THIS PRODUCT IS A GIFT FROM THE AMERICAN PEOPLE

HIGH ENERGY BISCUITS

THIS PRODUCT IS A GIFT FROM THE AMERICAN PEOPLE

HIGH ENERGY BISCUITS

NUTRITION INFORMATION

Nutrition	Per 100 gram	Nutrition	Per 100 gram	Nutrition	Per 100 gram
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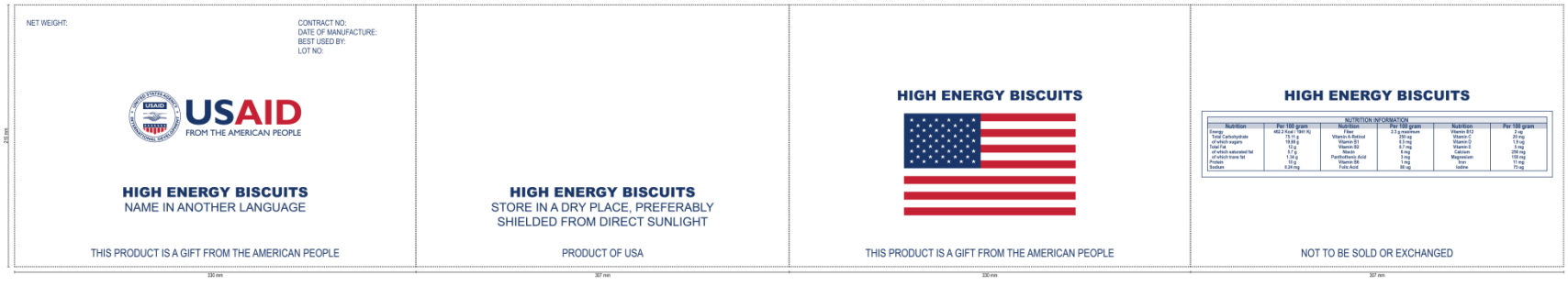
NOT TO BE SOLD OR EXCHANGED


NET WEIGHT:
CONTRACT NO:
DATE OF MANUFACTURE:
BEST USED BY:
LOT NO:
USAID
FROM THE AMERICAN PEOPLE
HIGH ENERGY BISCUITS
NAME IN ANOTHER LANGUAGE
THIS PRODUCT IS A GIFT FROM THE AMERICAN PEOPLE
HIGH ENERGY BISCUITS
STORE IN A DRY PLACE, PREFERABLY
SHIELDED FROM DIRECT SUNLIGHT
PRODUCT OF USA
HIGH ENERGY BISCUITS
THIS PRODUCT IS A GIFT FROM THE AMERICAN PEOPLE
HIGH ENERGY BISCUITS
NUTRITION INFORMATION
Nutrition
Per 100 gram
Energy
460.2 Kcal / 1941 kj
Total Carbohydrate
75.15 g
of which sugars
19.88 g
Total Fat
12 g
of which saturated fat
5.1 g
of which trans fat
1.39 g
Protein
10 g
Sodium
0.24 mg
Fiber
2.3 g maximum
Vitamin A Retinol
250 ug
Vitamin B1
0.5 mg
Vitamin B2
0.7 mg
Vitamin B3
5 mg
Panthothenic Acid
5 mg
Vitamin B6
1 mg
Folic Acid
90 ug
Vitamin B12
3 ug
Vitamin C
20 mg
Vitamin D
1.9 ug
Vitamin E
5 mg
Calcium
250 mg
Magnesium
100 mg
Iron
11 mg
Iodine
75 ug
NOT TO BE SOLD OR EXCHANGED
215 mm
330 mm
307 mm
330 mm
307 mm