FDA COMPLIANCE

All FSI polypropylene filtration media product lines are manufactured using FDA compliant materials under the Federal Food, Drug, and Cosmetic Act under regulations:

21 C.F.R. 177.1520 (c) 1.1
21 C.F.R. 177.2800
21 C.F.R. 178.3400

Provided that the end user is complying with FDA's good manufacturing practices under Title 21 C.F.R. 174.5.

(b) (6)

Quality Assurance Manager

5/30/13
date

KOCH MEMBRANE SYSTEMS

KMS HFK□ -131 FOOD □ DAIRY UF ELEMENTS

Ultrafiltration 4", 6" and 8" Spiral Element Series

PRODUCT DESCRIPTION

Membrane Chemistry:	Proprietary semi-permeable polyethersulfone (PES)
Membrane Type:	HFK™-131 with observed separation range of 10,000 Daltons
Construction:	Sanitary spiral wound element with net outer wrap
Regulatory Status:	Conform to USDA 3-A standards and FDA regulations (CFR Title 21)
Options:	Diameter: 3.8", 4.3", 6.3", 6.4", 8.0", or 8.3"
	Length: 33", 35.5", or 38"
	Feed Spacer: N (31 mil), V (46 mil), H (62 mil), or F (80 mil), D (100 mil)
	Outer wrap: Controlled (e.g. NYV) or trimmable (e.g. NYT)

SPECIFICATIONS

Model	Active Membrane Area									
	NYV/T Spacer (31 mil)		VYV/T Spacer (46 mil)		HYV/T Spacer (62 mil)		FYV/T Spacer (80 mil)		DYV/T Spacer (100 mil)	
	ft²	(m²)	ft²	(m²)	ft²	(m²)	ft²	(m²)	ft²	(m²)
3838 HFK-131	72	(6.7)	58	(5.4)	45	(4.2)	-	-	-	-
4333 HFK-131	93	(8.6)	73	(6.8)	55	(5.1)	44	(4.1)	-	-
4336 HFK-131	95	(8.8)	79	(7.3)	59	(5.5)	-	-	-	-
4338 HFK-131	102	(9.5)	81	(7.5)	-	-	-	-	-	-
6338 HFK-131	228	(21.2)	180	(16.7)	142	(13.2)	119	(11.1)	102	(9.5)
6438 HFK-131	228	(21.2)	180	(16.7)	142	(13.2)	119	(11.1)	-	-
8038 HFK-131	358	(33.2)	276	(25.6)	215	(20.0)	-	-	-	-
8338 HFK-131	-	-	308	(28.6)	241	(22.4)	194	(18.0)	-	-

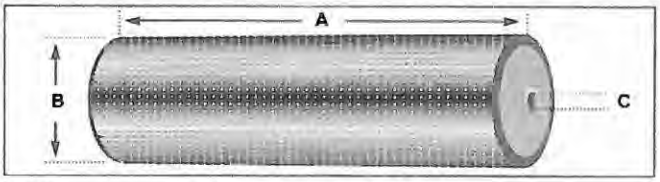
Not all combinations are available.
6438 elements are only available in controlled configuration. 6338 elements are only available in trimmable configuration.

OPERATING AND DESIGN INFORMATION*

Typical Operating Pressure:	30 - 120 psi (2.1 - 8.3 bar)
Maximum Operating Pressure:	140 psi (9.7 bar)
Operating Temperature Range:	41 - 131°F (5 - 55°C)
Cleaning Temperature Range:	105 - 122°F (40 - 50°C)
Allowable pH - Continuous Operation:	2.0 - 10.0
Allowable pH - Clean-In-Place (CIP):	1.8 - 11.0
Design Pressure Drop Per Element:	N spacer: 12-15 psi (0.8-1.0 bar)
	V spacer: 15-20 psi (1.0-1.4 bar)
	H or F spacer: 15-25 psi (1.0-1.7 bar)
Design Pressure Drop Per Vessel (3 in series):	N spacer: 36-45 psi (2.5-3.1 bar)
	V spacer: 45-60 psi (3.1-4.1 bar)
	H or F spacer: 45-75 psi (3.1-5.2 bar)
Design Pressure Drop Per Vessel (4 in series):	N spacer: 48-60 psi (3.3-4.1 bar)
	V spacer: 60-68 psi (4.1-4.7 bar)

* Consult KMS Process Technology Group for specific applications.

NOMINAL DIMENSIONS



Model	A	B	C
	inches (mm)	inches (mm)	inches (mm)
3838 HFK-131	38.0 (965)	3.8 (96)	0.831 (21.1)
4333 HFK-131	33.0 (838)	4.3 (109)	0.831 (21.1)
4336 HFK-131	35.5 (902)	4.3 (109)	0.831 (21.1)
4338 HFK-131	38.0 (965)	4.3 (109)	0.831 (21.1)
6338 HFK-131	38.0 (965)	6.3 (160)	1.138 (28.9)
6438 HFK-131	38.0 (965)	6.4 (162)	1.138 (28.9)
8038 HFK-131	38.0 (965)	7.9 (201)	1.138 (28.9)
8338 HFK-131	38.0 (965)	8.3 (211)	1.138 (28.9)

Note: Not all combinations are available.

Membrane Characteristics:

- The membrane used in these modules consists of a semipermeable polyethersulfone (PES) layer on a polyester backing material.
- Pure water flux of these PES HFK-131 membranes is 1.0-2.2 gfd/psi (24-53 l/m²/h/bar) at 77°F (25°C).
-

Operating Limits:

- **Operating Pressure:** Maximum operating pressure is 140 psi (9.7 bar).
- **Permeate Pressure:** Permeate pressure should not exceed baseline (concentrate) pressure at any time (including on-line, off-line and during transition). Reverse pressure will damage the membrane.
- **Differential Pressure:** The maximum differential pressures per element are listed on the front of this document, including design values for multi-element housings.
- **Temperature:** Maximum operating temperature is 131°F (55°C). Maximum cleaning temperature is 122°F (50°C).
- **pH:** Allowable range for continuous operation is 2.0 to 10.0. Allowable pH range for cleaning is 1.8 to 11.0.

Water Quality for Cleaning & Diafiltration:

- **Turbidity and SDI:** Maximum feed turbidity is 1 NTU. Maximum feed SDI is 5.0 (15-minute test).
- **Guidelines:** Please refer to the KMS "Water Quality Guidelines for CIP and Diafiltration" for more detailed information.

Chlorine and Chemical Exposure:

- Adherence to cleaning and sanitizing procedures including chemical concentrations, pH, temperature, and exposure time is necessary to achieve maximum useful element life. Accurate records should be maintained.
- KMS standard cleaning procedures for dairy applications should be followed. Recommended chlorine exposure time at the defined conditions is 30 minutes per day.
- Residual chlorine concentration during cleaning cycle (CIP) should be 150 ppm @ pH 10.5 or higher. Chlorine concentration should never exceed 200 ppm.
- Chlorine should only be added to the cleaning solution after the pH has been adjusted to 10.5 or higher.
- Iron or other catalyzing metals in the presence of free chlorine or hydrogen peroxide will accelerate membrane degradation.
- Sanitizing should be done only after a complete cleaning cycle and with water of acceptable quality. Refer to cleaning instructions and feedwater quality technical bulletins.

Cationic Polymers and Surfactants:

HFK-131 membranes may be irreversibly fouled if exposed to cationic (positively charged) polymers or surfactants. Exposure to these chemicals during operation or cleaning is not recommended and will void the warranty.

Lubricants:

For element installation, use only water or glycerin to lubricate seals. The use of petroleum or vegetable-based oils or solvents may damage the element and will void the warranty.

Supplemental Technical Bulletins:

- UF Element Cleaning Procedures
- Water Quality Guidelines for CIP and Diafiltration

Service and Ongoing Technical Support:

KMS has an experienced staff available to assist end-users and OEM's for optimization of existing systems and development of new applications. KMS also offers a complete line of KOCHKLEEN® membrane pretreatment, cleaning, and maintenance chemicals.

KMS Capability

KMS is the leader in crossflow membrane technology, manufacturing reverse osmosis, nanofiltration, microfiltration, and ultrafiltration membranes and membrane systems. The industries we serve include food, dairy and beverage, semiconductors, automotive, water and wastewater, chemical and general manufacturing. KMS adds value by providing top quality membrane products and by sharing our experience in the design and supply of thousands of crossflow membrane systems worldwide.

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• San Diego, California • Aachen, Germany • Lyon, France • Madrid, Spain • Milan, Italy • Wijnegem, Belgium • Beijing & Shanghai, China • Mumbai, India •
• Melbourne, Australia • Singapore • Sao Paulo, Brazil • Manama, Kingdom of Bahrain

Document Information

Material Name	:	Cheese Salt
Prepared by	:	Jo Steven
Supersedes	:	V3

Status :

Draft	Approved
	X

Material Identification

This product can be identified in various systems as the following:

System Name	Item name (as per M3)	Coding
Synlait ERP	Cheese Salt	RMIN00049
Dominion Salt	-	PDV Cheese Grade Salt

Material Attributes

Description	:	Pure dried vacuum (PDV) salt, with anticaking agent sodium ferrocyanide (E535). **Note: Anticaking agent not allowed for use for infant products**
Alternative name	:	Sodium Chloride, NaCl
Supplier	:	Dominion Salt, New Zealand; Production Site: Lake Grassmere (LG), or Mt Maunganui (MM)
Allergen(s)	:	None
Contains Dairy Material	:	No
Traceability	:	Production Batch
Grade	:	Food Grade
Ingredients	:	Salt, Sodium Ferrocyanide (E535)

Documentation Requirements

This product needs to comply with following requirements:

Documents Required	Frequency
Certificate of Analysis (CoA)	Every shipment
HALAL	On request
KOSHER	On request
GMO-free certificate/ declaration	On request
MSDS	On request
Allergen documentation	On request
Dairy material declaration as required (SOR / FIC & accompanying Health Cert.) Must contain the following attestations: Were derived only from animals and processed in countries which are recognised by the OIE World Organisation for Animal Health as free of foot and mouth disease, with or without vaccination; Were derived only from animals which meet OIE requirements for lumpy skin disease, sheep pox and goat pox freedom; The country of origin has controls in place to ensure that only healthy animals are used for milk production	N/A
Other technical documents	On request
Packing list	Every shipment

This product needs to be manufactured and packed according to HACCP regulations

General Composition

Parameter	Unit	Typical	Min	Max	Required on CoA	Comment	Testing plan (Synlait)*
Sodium Chloride	% DM		99.6		On Request	Monthly Monitoring	High + SL
Moisture	%			0.2	Yes	-	Low
Sodium Ferrocyanide	ppm			15	Yes	May be reported on CoA as Anticaking Agent $[Fe(CN)_6]^{4-}$	Low
Matter insoluble in water	ppm			300	On Request	-	Low

Physical and Chemical Attributes

Parameter	Unit	Typical	Min	Max	Required on CoA	Comment	Testing plan (Synlait)*
Scorched Particles (Black specks)	Disc/50g			A	Yes	ADMI Method. May be reported on CoA as visual foreign matter	Low
Other Foreign Matter	/50g		Absent		Yes	May be reported on CoA as unacceptable foreign matter absent	Low
Particle size passing 212µm	%			2	Yes	-	N/A
Particle size passing 850µm	%		100		Yes	-	N/A

Sensory Attributes

Parameter	Description	Required on CoA	Testing plan (Synlait)*
Appearance	White, relatively coarse uniformly sized crystals. No caking that does not break up under moderate pressure.	On Request	High (Internal Evaluation) + SL
Odour	Odourless - no foreign or off-odours	On Request	High (Internal Evaluation) + SL

Contaminants and Residues

Parameter	Unit	Limit (Max)	Required on CoA	Comment	Testing plan (Synlait)*
Cadmium (Cd)	mg/kg	0.2	Yes	Yearly Monitoring	Low
Arsenic (As)	mg/kg	0.5	Yes	Yearly Monitoring	Low
Copper (Cu)	mg/kg	2	On Request	Monthly Monitoring	N/A
Iron (Fe)	mg/kg	10	On Request	Monthly Monitoring	N/A
Lead (Pb)	mg/kg	1	Yes	Yearly Monitoring	Low
Mercury (Hg)	mg/kg	0.05	Yes	Yearly Monitoring	Low
Alkalinity (as Na_2CO_3)	mg/kg	300	On Request	Monthly Monitoring	N/A

*Test plan for Synlait RM test procedure: high = test every time; low = reduced test can be used when applicable; N/A: not tested (e.g. due to test method capability); +SL= tested when shelf-life extension is required.

Packaging

Pack Size	Descriptions
25 kg	Plastic (Polyethylene) Bag. Packaging must be suitable for food contact.

Labelling Information

This information is required on the label in accordance with the Australia New Zealand Food Standards Code:

- Product name
- Manufacturer's name and address
- Ingredient list (if applicable) – on the label or in accompanying documentation
- Date of manufacture
- Expiry or Best Before Date
- Weight or quantity
- Lot/batch number

Storage Requirements

Shelf life - unopened	:	60 months (5 years) from date of manufacture
Storage instructions	:	Store in dry, cool conditions, away from direct sunlight in original sealed packaging.
Shelf-life - opened	:	Shelf life = first opening date + 6 months OR original manufacturer shelf life, whichever is shortest. Must be stored in well-sealed foil pouch at recommended temperatures. Pre-weighed: max. 14 days when stored protected from light (in black plastic bag or similar) at recommended temperature.

Logistic Requirements

Method of shipping(s)	:	Road / Sea freight
Estimated lead time	:	2 - 4 weeks
Shipping requirement(s)	:	CoA and packing slip to accompany goods

Revision History

Version	Nature of Change	Initiated by	Approved by	Date dd-mm-yyyy
1	New Specification	KW	IH	07/09/12
2	Amend contaminant levels in accordance to GB update and customer requirement	KW	IH	08/02/13
3	Add new supplier. Ensure has both FCC and GB requirements	KW	TJ	17/04//15
4	Update information into new template and update suppliers. Add foreign matter requirements. Align units with current CoA	JS	TJ	23/11/15

PRODUCT SPECIFICATION

(Appendix 2 of the NZDI Salt Specification)

PURE DRIED VACUUM SALT (PDV)

DominionSalt

Head Office & N.I. Refinery

89 Totara Street, Mount Maunganui, New Zealand
PO Box 4249, Mount Maunganui South
Phone: 64 7 5756193 Fax: 64 7 575 3017
Email: sales@domsalt.co.nz
Website: www.domsalt.co.nz

Lake Grassmere & S.I. Refinery

Kaparu Road, Marlborough, New Zealand
PO Box 81, Seddon
Phone: 64 3 575 7021 Fax: 64 3 575 7002
Email: sales@domsalt.co.nz
Website: www.domsalt.co.nz

CHEESE SALT			
COMPONENTS	**NZ Dairy Salt Specification**	**TYPICAL**	**DSL Test Method** *(Reference Method)*
Sodium Chloride as NaCl - Minimum moisture free	Min 99.6 %	>99.8%	Calculated by difference
Moisture Content	Max 0.2%	0.02%	DSL Pt. 12 *(BS 7319:Part 2:1990)*
Matter Insoluble in water	Max 300 mg/kg	<10 mg/kg	DSL Pt. 11 *(BS 7319:Part 3:1990)*
Foreign matter[1]	ADMI - A	A	DSL Pt. 8 *(In-house)*
Sulphate as Na_2SO_4	Max 3000 mg/kg	<1500 mg/kg	DSL Pt. 14 *(BS 7319:Part 4:1990)*
Calcium as Ca	Max 100 mg/kg	<20 mg/kg	DSL Pt. 5 *(BS 7319:Part 5:1990)*
Magnesium as Mg	Max 100 mg/kg	<15 mg/kg	" "
Cadmium as Cd	Max 0.2 mg/kg	<0.01 mg/kg	DSL Pt. 4 *(BS 7319:Part 6:1990)*
Arsenic as As	Max 0.5 mg/kg	<0.01 mg/kg	DSL Pt. 2 *(BS 4404:1968)*
Copper as Cu	Max 2 mg/kg	<0.1 mg/kg	DSL Pt. 4 *(BS 7319:Part 7:1990)*
Lead as Pb	Max 1 mg/kg	<0.1 mg/kg	DSL Pt. 4 *(BS 7319:Part 8:1990)*
Mercury [2] as Hg	Max 0.05 mg/kg	<0.01 mg/kg	ICP *(BS 7319:Part 9:1990)*
Alkalinity as Na_2CO_3	Max 300 mg/kg	<100 mg/kg	DSL Pt. 1 *(BS 7319:Part 10:1990)*
Iron as Fe	Max 10 mg/kg	<1.0 mg/kg	DSL Pt. 4 *(BS 7319:Part 11:1990)*
Food Additives [3]:			
Additive 535 as $[Fe(CN)_6]^{4-}$	Max 15 mg/kg	4-6 mg/kg	DSL Pt. 9 *(BS 7319:Part 12:1990)*

Notes: < Less than > Greater than ppm = mg/kg = (% x 10,000)

1. "Foreign matter" is not defined in the FSANZ Code Volume 2, therefore reference "7CFR 2858.267 Scorched Particle Standards for Dry Milks" has been adopted to quantify the level of sediment. A photocopy of this reference is available on request to the Works Chemist.
2. Test performed on incoming bulk salt shipment before refining.
3. As specified in FSANZ Food Standards Code Volume 2, Part 1.3 schedule 1. (Available at website: www.foodstandards.govt.nz)

GRADE DESCRIPTION:

High purity certified vacuum salt especially prepared to be of relatively coarse crystals with a narrow grain size range. Strictly prepared in batch lots to optimise grain size uniformity. Suitable for salting in some mechanical cheese manufacturing plants using accurate pneumatic salt conveying equipment, which are sensitive to a wide or variable range of grain sizes.

Country of origin: Product of New Zealand

NUTRITIONAL INFORMATION

Component	Per 100g
Saturated Fat	Nil g
Mono Unsaturated Fat	Nil g
Poly Unsaturated Fat	Nil g
Trans Fatty Acids	Nil g
	Typically
Sodium	39.1g min
Chloride	60.5g min
Calcium	<0.4 - 4 mg
Potassium	2-4 mg
Iron	<1 mg
Cholesterol	Nil mg
Dietary Fibre – soluble	Nil mg
Dietary Fibre - Insoluble	Nil mg

GRAIN SIZE: 100% passing 850 microns
0 - 2% passing 212 microns

BULK DENSITY: Nominally: loose 1.25g/ml, compacted 1.43g/ml

COMPLIANCE:

- ***Certified to NZDI Salt Specification***
- Complies with BS998:1990 Vacuum Salt for Food Use
- Complies with FSANZ Food Standards Code Volume 2 Standard 2.10.2/Clause 2
- NOT a genetically modified food as defined under 1.5.2 of the FSANZ Standards Code Volume 2
- *Is Free from known Allergens*
- *Halal Certified*
- *Kosher Certified*
- *Dominion Salt is ISO 9001 certified*

PACK:

Bulk Bag Woven Polypropylene with Polyethylene liner (Weight by arrangement)
Bulk Bag Woven Polypropylene with Polyethylene barrier layer laminated to inside face of woven material.
25kg Polyethylene Bag (no outer)
Packaging material complies with US FDA regulations Title 21, parts 170-199
Print colour: Bulk Bag - Blue 072
25kg Bag - Spot Orange 021

Pallets:

Small packs: Standard pallet configuration is 48 x 25 kg bags (1.2 tonnes per pallet) The salt is stretch wrapped and capped on pallets with a pallet sheet between the pallet and the salt
Bulk Bags: Standard configuration is one bulk bag per pallet

Issue Date: 20.08.09
Issue No: 13

Raw Material Specification Synlait Skim Milk

	Month	Limits	September	March	June	September	March	June	Dec	Sept	Dec	Mar
	Year		2012	2013	2013	2013	2014	2014	2014	2015	2015	2016
Moisture	% m/m		90.69	90.34	90.98	90.67	90.02	90.84	90.58	90.82	90.53	90.63
Fat	% m/m	<0.15	<0.1	0.111	0.086	0.07	0.09	0.07	0.06	0.07	0.09	0.1
Protein	% m/m	>3.5	3.64	4.11	3.6	3.62	4.25	3.78	3.82	3.7	3.81	3.91
Lactose/carbo	% m/m		4.89	4.649	4.584	4.85	4.85	4.53	4.76	4.61	4.77	4.6
Ash	% m/m	<1.0	0.78	0.79	0.75	0.79	0.79	0.78	0.78	0.8	0.8	0.76
Total Solids (TS)	% m/m		9.31	9.66	9.02	9.33	9.98	9.16	9.42	9.18	9.47	9.37
MICRONUTRIENT												
Calcium	mg/100g	>100	130	140	130	140	140	130	140	120	130	130
Chloride	mg/100g	<200	96	102	106	90	100	107	95	89	94	102
Copper	ppm											<0.028
Copper	µg/100mL		7.8	5	7.5	4.1	3.2					
Iron	ppm		<0.025	0.027	<0.025	<0.025	0.023					<0.25
Iodine	ug/100g		7.5	4.7	15	5.2	4.8	10.0	6.2	0.09 mg/kg	3.5	3.6
Potassium	mg/100g		160	150	160	160	150	150	170	150	160	150
Manganese	mg/100g		<1.8	3.1	2.5	<1.75	3.3					<1.8 ug/100g
Magnesium	mg/100g		10	13	11	11	13	12	12	10	11	12
Sodium	mg/100g	<100	34	37	38	31	36	38	34	30	31	36
Phosphorus	mg/100g	<200	110	110	99	110	100	100	110	100	100	98
Selenium	mg/100g			1.5			1.5					1.3 ug/100g
Zinc	mg/100g		0.45	0.47	0.43	0.41	0.44	0.44	0.45	0.41	0.41	0.39
Vit B1 (Thiamine)	µg/100mL		<15.7	42.49	25.18	19.67	28.40	22.82	34.00	27.30	21.00	24.00
Vit B2 (Riboflavin)	µg/100mL		227	226	201	224	255	221	227	227	215	265
Vit B3 (Niacin)	µg/100mL			<150								
Vit B5 (Pantothenic Acid)	µg/100mL		351	200	400	500	400	500	500		0.42 mg/100	226
Vit B6 HCl	µg/100mL		29	33	33	28	32.0	30.5	39.0	29	35	32
Vit B12	µg/100mL		0.42	0.578	<0.2	0.51	0.529	0.656	0.537	0.5	0.587	0.558
Vit C	mg/100mL		<1	<1	<1	<1						
Biotin	µg/100mL		<8	<8		<8						
Total L-Carnitine	mg/100g		2.34	1.84	1.5	1.7	2.4	2.7	1.9	2.6	1.5	2.5
Choline	mg/100mL		10	13	11	11	5.7	15.0	11	9	10	9.25
Folic acid	µg/100mL			<8	<8							
Inositol	mg/100g		4.8	4.5	4.2	4.3	4.9	5.6	5	5.4	6.5	6.15
CONTAMINANT												
Total Heavy Metals	mg/kg	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
Nitrate	mg/L	<1	0.1	<1	<1	<0.2	0.4	0.4	<0.2	<0.2	<0.2	<1
Nitrite	mg/L	<1	0.01	0.1	0.08	0.09	0.05	0.05	0.04	0.03	0.05	<0.03
Inhibitory substances	IU/mL	<0.0025	<0.0025	<0.0025	<0.0025	<0.0025	<0.0025	<0.0025		<0.0025		

Table 1 – Processing Aid Comparison Morinaga vs Synlait Bovine Lactoferrin

Table 2. Processing Aids and Chemicals Used in the Production of Cow's Milk-Derived Lactoferrin (cMDLf) - Page #10 (27 of 217) from GRAS 465.pdf			**Synlait Milk Ltd Spray Dried Bovine Lactoferrin**	
Processing Aid or Chemical	**Manufacturer**		**Processing Aid or Chemical**	**Manufacturer**
	At Milei for cMDLf-1, cMDLf-2	**At Riedlingen for cMDLf-2**		
Demineralized water	Milei	Riedlingen plant	Demineralized water	In-house RO water
Sodium chloride (NaCl)	Herkommer & Bangerte	Herkommer & Bangerte	Sodium chloride (NaCl)	Dominion Salt, New Zealand
Hydrochloric Acid (HCl)	Herkommer & Bangerte	Not used	Hydrochloric Acid (HCl)	Not applicable
CM Sephadex C-50 or SP Sepharose Big Beads	GE Healthcare	GE Healthcare	Resins for ion exchange	GE Healthcare
Filter cloth (1um)	Wolftechnik Filtersysteme	Wolftechnik Filtersysteme	Ultrafiltration	Koch Membranes
Filter cloth (5um)	Wolftechnik Filtersysteme	Not used	Microfiltration	Tami
GR61PP Membrane	Alfa Laval	Not used		

GE Healthcare

Certificate of Analysis

Product:

SP Sepharose™ Big Beads Food Grade

Code Numbers:
11-0008-29
11-0008-30
11-0008-31

Lot No: 10163437

Test/Characteristic:		Limits:	Results:
1	**Function** Elution volume; ml		
1.1	Wheat Germ Lectin - peak 1 - peak 2 - peak 3	 60 – 88 80 – 122 96 – 138	 71 98 110
1.2	β-Lactoglobulin	147 – 189	157
2	**Total capacity** mmol H^+ / ml packed gel	0.18 – 0.25	0.23
3	**Flow rate at 0.1 MPa**; cm/h	1200 – 1800	1450
4	**Particle size distribution** Volume share within 100 – 300 µm; %	min. 80	98
5	**Microbial contamination** Colony Forming Units / ml suspension	max. 100	0

Manufactured in compliance with our ISO 9001 certified quality management system.

Approval date (Year-Month-Day): 2013-06-03

Expiry date (Year-Month): 2018-05
Manufacturing date (Year-Month): 2013-05

Tests and limits according to AS 45-6015-84 Ed. AB

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Reg.No. SE 55 61 08 1919 01

Quality Assurance
Issued (Year-Month-Day) 2013-06-03 by Sten Pettersson

This document has been electronically produced and is valid without a signature.

28-9653-19 / AC
DOC1103901 / 1
Valid from 2012-02-24

GE Healthcare

SAFETY DATA SHEET

New Zealand

Section 1. Identification

Product name **SP Sepharose™ Big Beads, Food Grade, 10 L**

Catalogue Number 11-0008-30

Other means of identification Not available.

Product type Liquid.

Identified uses
Laboratory chemicals Liquid chromatography. Research and Development

Supplier

GE Healthcare UK Ltd
Amersham Place
Little Chalfont
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England
+44 0870 606 1921

GE Healthcare Bio-Sciences
8 Tangihua Street
Auckland 1010

Person who prepared the MSDS :
msdslifesciences@ge.com

Emergency telephone number (with hours of operation)
0800 733 893
(10am - 7pm)

Section 2. Hazards identification

HSNO Classification 3.1 - FLAMMABLE LIQUIDS - Category C
6.4 - EYE IRRITATION - Category A (Irritant)

This material is classified as hazardous according to criteria in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 and has been classified according to the Hazardous Substances (Classifications) Regulations 2001.

This material is classified as a dangerous good according to criteria in New Zealand Standard 5433:2007 Transport of Dangerous Goods on Land.

GHS label elements

Signal word Warning

Hazard statements Flammable liquid and vapor.
Causes serious eye irritation.

Precautionary statements

Prevention Wear protective gloves: 1-4 hours (breakthrough time): butyl rubber, neoprene. Wear eye or face protection: Recommended: safety glasses with side-shields. Keep away from ignition sources such as heat/sparks/open flame. - No smoking. Use explosion-proof electrical, ventilating, lighting and all material-handling equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Keep container tightly closed.

Response IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Wash hands after handling.

Storage Store in cool/well-ventilated place.

Disposal Dispose of contents and container in accordance with all local, regional, national and international regulations.

Symbol

Other hazards which do not result in classification Not available.

Section 3. Composition/information on ingredients

Substance/mixture	Mixture
Other means of identification	Not available.
CAS number/other identifiers	
CAS number	Not applicable.
EC number	Mixture.
Product code	11-0008-30

Ingredient name	%	CAS number
Ethanol	14 - 19	64-17-5

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Inhalation	If inhaled, remove to fresh air. Get medical attention if symptoms appear.
Ingestion	Do not ingest. Get medical attention if symptoms appear.
Skin contact	Wash with soap and water. Get medical attention if irritation develops.
Eye contact	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Inhalation	No known significant effects or critical hazards.
Ingestion	Irritating to mouth, throat and stomach.
Skin contact	No known significant effects or critical hazards.
Eye contact	Causes serious eye irritation.

Over-exposure signs/symptoms

Inhalation	No specific data.
Ingestion	No specific data.
Skin	No specific data.
Eyes	Adverse symptoms may include the following: pain or irritation watering redness

Indication of immediate medical attention and special treatment needed, if necessary

Specific treatments	Not available.
Notes to physician	No specific treatment. Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Protection of first-aiders	No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable	Use dry chemical, CO_2, water spray (fog) or foam.
Not suitable	Do not use water jet.
Specific hazards arising from the chemical	Flammable liquid and vapor. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion. Runoff to sewer may create fire or explosion hazard.
Hazardous thermal decomposition products	Decomposition products may include the following materials: carbon dioxide carbon monoxide
Hazchem code	Not available.

Special precautions for fire-fighters	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.
Special protective equipment for fire-fighters	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment (see Section 8).
Environmental precautions	Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill	Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Use spark-proof tools and explosion-proof equipment. Dispose of via a licensed waste disposal contractor.
Large spill	Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see section 13). Use spark-proof tools and explosion-proof equipment. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see section 1 for emergency contact information and section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling	Put on appropriate personal protective equipment (see Section 8). Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use only non-sparking tools. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Empty containers retain product residue and can be hazardous. Do not reuse container.
Conditions for safe storage, including any incompatibilities	Store between the following temperatures: 4 to 30°C (39.2 to 86°F). Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Ethanol	**NZ OSH (New Zealand, 1/2002).** WES-TWA: 1880 mg/m³ 8 hour(s). WES-TWA: 1000 ppm 8 hour(s).

Recommended monitoring procedures	If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment.
Appropriate engineering controls	Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.
Environmental exposure controls	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures	Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
Respiratory protection	Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator. Recommended: A respirator is not needed under normal and intended conditions of product use.
Hand protection	1-4 hours (breakthrough time): butyl rubber, neoprene
Eye protection	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. Recommended: safety glasses with side-shields
Skin protection	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Recommended: lab coat

Section 9. Physical and chemical properties

Appearance	
Physical state	Liquid. [and Suspension.]
Color	solution : Colorless. / Suspension. : White.
Odor	Sweetish. Alcohol-like. [Slight]
Odor threshold	180 ppm
pH	Not available.
Melting point	Not available.
Boiling point	Not available.
Flash point	Closed cup: 38 to 43°C (100.4 to 109.4°F)
Burning rate	Not applicable.
Burning time	Not applicable.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Lower and upper explosive (flammable) limits	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility	Easily soluble in the following materials: cold water and hot water.
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
SADT	Not available.
Viscosity	Not available.
Aerosol product	
Type of aerosol	Not applicable.
Heat of combustion	Not available.
Ignition distance	Not applicable.
Enclosed space ignition - Time equivalent	Not applicable.
Enclosed space ignition - Deflagration density	Not applicable.
Flame height	Not applicable.
Flame duration	Not applicable.

Section 10. Stability and reactivity

Chemical stability	The product is stable.
Possibility of hazardous reactions	Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	Avoid all possible sources of ignition (spark or flame). Do not pressurize, cut, weld, braze, solder, drill, grind or expose containers to heat or sources of ignition.
Incompatible materials	Reactive or incompatible with the following materials: oxidizing materials
Hazardous decomposition products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on the likely routes of exposure

Inhalation	No known significant effects or critical hazards.
Ingestion	Irritating to mouth, throat and stomach.
Skin contact	No known significant effects or critical hazards.
Eye contact	Causes serious eye irritation.

Symptoms related to the physical, chemical and toxicological characteristics

Inhalation	No specific data.
Ingestion	No specific data.
Skin contact	No specific data.
Eye contact	Adverse symptoms may include the following: pain or irritation watering redness

Delayed and immediate effects and also chronic effects from short and long term exposure

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Ethanol	LC50 Inhalation Vapor	Rat	124700 mg/m3	4 hours
	LD50 Oral	Rat	7 g/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Ethanol	Eyes - Mild irritant	Rabbit	-	-	-
	Eyes - Moderate irritant	Rabbit	-	-	-
	Eyes - Severe irritant	Rabbit	-	-	-
	Skin - Mild irritant	Rabbit	-	-	-
	Skin - Moderate irritant	Rabbit	-	-	-

Conclusion/Summary

Skin	Repeated exposure may cause skin dryness or cracking.

Sensitization

Not available.

Potential chronic health effects

General	No known significant effects or critical hazards.
Inhalation	No known significant effects or critical hazards.
Ingestion	No known significant effects or critical hazards.
Skin contact	No known significant effects or critical hazards.
Eye contact	No known significant effects or critical hazards.
Carcinogenicity	No known significant effects or critical hazards.
Mutagenicity	No known significant effects or critical hazards.
Teratogenicity	No known significant effects or critical hazards.
Developmental effects	No known significant effects or critical hazards.
Fertility effects	No known significant effects or critical hazards.

Chronic toxicity

Not available.

Carcinogenicity

Not available.

Mutagenicity

Not available.

Teratogenicity

Not available.

Reproductive toxicity

Not available.

Specific target organ toxicity

Not available.

Aspiration hazard

Not available.

Numerical measures of toxicity

Acute toxicity estimates

Not available.

Other information Adverse symptoms include the following: kidney abnormalities, liver abnormalities
Adverse symptoms may include the following: central nervous system depression

Section 12. Ecological information

Ecotoxicity No known significant effects or critical hazards.

Aquatic and terrestrial toxicity

Product/ingredient name	Result	Species	Exposure
Ethanol	Acute EC50 2000 ug/L Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 25500 ug/L Marine water	Crustaceans - Artemia franchiscana - LARVAE	48 hours
	Acute LC50 42000 ug/L Fresh water	Fish - Oncorhynchus mykiss	4 days
	Chronic NOEC <6.3 g/L Fresh water	Daphnia - Daphnia magna	48 hours

Persistence/degradability

Product/ingredient name	Test	Result	Dose	Inoculum
Ethanol	-	100 % - Readily - 20 days	-	-

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
Ethanol	-	-	Readily

Bioaccumulative potential

Product/ingredient name	$LogP_{ow}$	BCF	Potential
Ethanol	-	0.66	low

Mobility in soil

Soil/water partition coefficient (K_{OC}) Not available.

Other adverse effects No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods

The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way. Significant quantities of waste product residues should not be disposed of via the foul sewer but processed in a suitable effluent treatment plant. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Classes	PG*
New Zealand Class	Not regulated.	-	-	-
ADG Class	Not regulated.	-	-	-
UN Class	Not regulated.	-	-	-
ADR/RID Class	Not regulated.	-	-	-
IATA Class	Not regulated.	-	-	-
		Remarks IATA Special Provision A 58 - Aqueous solutions containing 24% or less alcohol by volume is not subject to these regulations.		
IMDG Class	Not regulated.	-	-	-

PG* : Packing group

Section 15. Regulatory information

New Zealand Inventory of Chemicals (NZIoC) All components are listed or exempted.

HSNO Approval Number HSR001144

HSNO Group Standard Not available.

HSNO Classification 3.1 - FLAMMABLE LIQUIDS - Category C
6.4 - EYE IRRITATION - Category A (Irritant)

Australia inventory (AICS) All components are listed or exempted.

Safety, health and environmental regulations specific for the product No known specific national and/or regional regulations applicable to this product (including its ingredients).

Section 16. Other information

History

Date of printing 12/16/2010.

Date of issue/ Date of revision 15 December 2010

Date of previous issue No previous validation.

Version 0.9

Key to abbreviations

ADN/ADNR = European Provisions concerning the International Carriage of Dangerous Goods by Inland Waterway
ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail
UN = United Nations

References Not available.

Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.
Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Part 7 Appendix 1

Customer Specification Sheet

Synlait Lactoferrin 5kg Reclosable Pouch PPRI01005

8 December 2015

Issue Number: 01

Amcor Item:	1044979
Customer Item Code:	PPRI01005

Product detail:

Customer	Synlait Milk Ltd
Description	SYN LACTOFERRIN 5KG
Material Structure description	Coated Polyester(14um)/ ink/adhesive/Foil(7um)/Nylon(15um) Polyethylene (90um)
Yield:	148.6gsm* Tolerance: +/-10gsm
Gauge:	133µm* Tolerance: +/-10µm
Estimated Oxygen Transmission Rate:	<0.3 cc/m^2/24hrs(100% O_2) 23°C/ 0% RH
Estimated Water Vapour Transmission Rate:	<0.3 g/m^2/24hrs 38°C 90% RH

* Excludes zipper

Amcor Flexibles Asia Pacific - ANZ
74 Branston Street; Hornby; Christchurch 8042; New Zealand
Ph: +64 3 349 1250 www.amcor.com

amcor

Customer Specification Sheet

Product and Packing Specifications:

Printing Process:	Flexographic.
Colour and Coatings:	To match customer approved standard.
Identification Labels:	Cartons: labels to state ID number, Item number, Description, Customer Code, Quantity, Carton number, Date and packer Pallet: Customer, product description, quantity, customer order number, customer stock number, pallet number, date, number of rolls, and Amcor job number.
Carton Handling:	Pouches should be kept out of direct natural light/sunlight and in a well-ventilated area. It is advantageous to condition the cartons to packing room temperature at least 24 hrs prior to use. At all times when not in use the carton should be sealed so performance is not impaired or contamination permitted.

Specification Data:

Customer Item Number	Amcor Item Number	Description		Length	Bags per Bundle	Bags per Carton
PPRI01005	1044979	SYN LACTOFERRIN 5KG	260X130X660 L81 RQPH	657	25	150

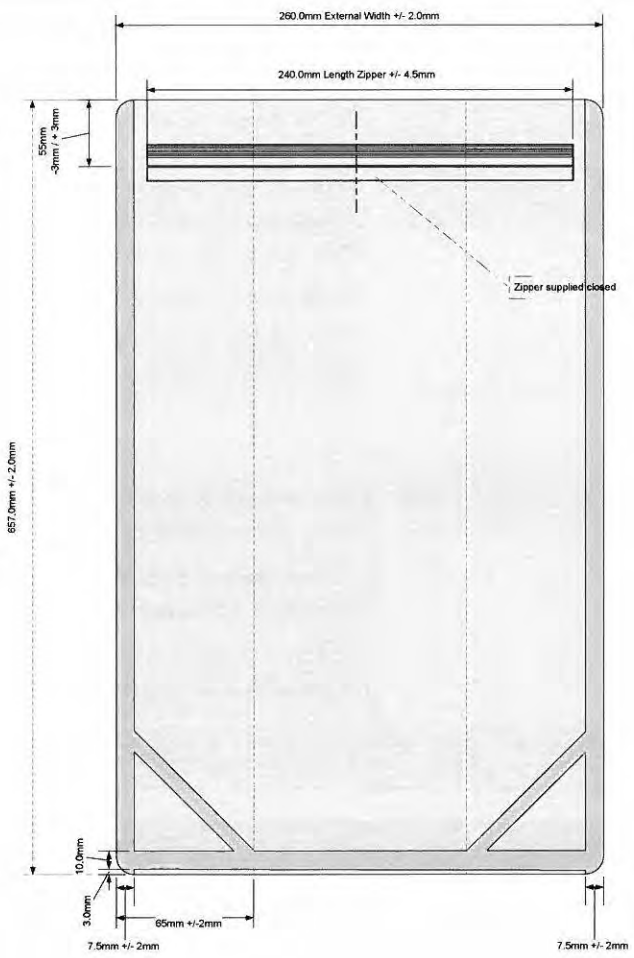
Reason for Revision:

Design change to 1 colour.

Amcor Flexibles Asia Pacific - ANZ
74 Branston Street; Hornby; Christchurch 8042; New Zealand
Ph: +64 3 349 1250 www.amcor.com

Customer Specification Sheet

Material Diagram: (not to scale)



Approved by (Amcor):	Approved by (Customer):
(b) (6)	
Position: Quality Manager	Position:
Date: 08/12/2015	Date:

Amcor Flexibles Asia Pacific - ANZ
74 Branston Street; Hornby; Christchurch 8042; New Zealand
Ph: +64 3 349 1250 www.amcor.com

PART 7:

APPENDIX 2: Synlait Manufacturing Certification And Registration Certificates

The data and information presented within Appendix 2 is Confidential to Synlait Milk Ltd and is **not generally available**.

NOTICE OF REGISTRATION

RISK MANAGEMENT PROGRAMME

Pursuant to section 22 of the Animal Products Act 1999, the Director-General has registered a risk management programme for:

Synlait Milk Limited

Located at:

1028 Heslerton Road, RD13 (Premises IDs S540,540)
RAKAIA

This risk management programme has been assigned the identifier:

SYNLAIT3/01

Risk management programmes manage hazards and other risk factors associated with animal products in order to ensure fitness for intended purpose, and are based on the principles of HACCP.

This registration is effective from 23/10/2015

Signed at Wellington on **19/01/2016**

(b) (6)

MINISTRY FOR PRIMARY INDUSTRIES
NEW ZEALAND

Maree Zinzley
Manager (Approvals Operations)
Acting under delegated authority
Ministry for Primary Industries

AsureQuality

This is to Certify

Synlait Milk Limited

1028 Heslerton Road, RD13, Rakaia, New Zealand

Has been assessed by AsureQuality Limited and found to comply with the standards based on:

Codex Alimentarius "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines" Reference CAC/RCP 1 – 1969, Rev. 4 – 2003, Annex.

The scope of this certificate includes the following products:
Anhydrous Milk Fat, Colostrum Products, Milk Powders, Milk Proteins, Nutritional Powders and Specialty Powders.

Manufacturer Identification Numbers: 540, S540

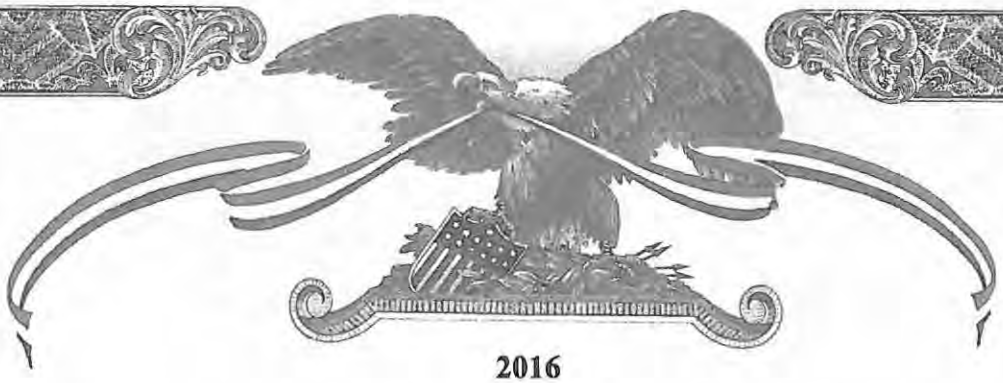
Certificate No:	DHACCP 059
Date of Issue:	2 February 2016
Valid Until:	1 February 2017

(b) (6)

John McKay
Chief Executive

Disclaimer: This certificate has been issued for commercial purposes only and is not intended to be supplied to competent authorities as a means of demonstrating compliance with New Zealand or importing country requirements.

This certificate remains the property of AsureQuality Ltd
7a Pacific Rise | Mt Wellington | Auckland 1741 | New Zealand
+64 9 573 8000 | www.asurequality.com | info@asurequality.com



2016

CERTIFICATE OF REGISTRATION

This certifies that:

Synlait Milk Ltd.
1028 Heslerton Road
RD 13, Rakaia, Canterbury 7783
New Zealand

is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as currently effective on the date hereof by Registrar Corp:

U.S. FDA Registration No.:	**15930127872**
U.S. Agent for FDA Communications:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

This certificate affirms that the above stated facility is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as effective by Registrar Corp as of the date hereof, and Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until December 31, 2016, unless such registration has been terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

(b) (6)

(b) (6)

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info@registrarcorp.com • www.registrarcorp.com

Russell K. Statman
Executive Director
Registrar Corp
Dated: September 9, 2015

PART 7:
APPENDIX 3: Analytical Methodology, Specifications And Results

The data and information presented within Appendix 3 (pages A3:10 - A3:32 is **generally available**.

Pages A3:2- A3: 9 and A3: 33 to A3:34 .... are Confidential to Synlait Milk Ltd and are **not generally available**

Standard Operating Procedure for Lactoferrin (LF) Analysis by RP-HPLC

-Applicable to products manufactured by Synlait Milk Limited

Initiated by: Jagan M Billakanti
Approved By: (b) (6)

Date effective: 25-02-2014

1. Purpose

To determine the purity of the lactoferrin content of liquid and powder lactoferrin products produced by cation exchange chromatography of milk.

2. Principle

HPLC analysis of bovine lactoferrin (LF) is carried out on a HPLC system equipped with a temperature controlled column oven and UV-Vis detector recording at 220 nm. Samples are diluted with deionized water, filtered through a 0.2 micron filter and injected onto a selected reversed-phase (RP)-HPLC column. Peaks present in the chromatogram recorded at 220 nm are integrated (3 – 9 minutes interval) and used for determination of lactoferrin purity. The LF content of the product is expressed as %LF. Identification of peaks is based on their retention times and absorption spectra at 220 nm when compared with a commercial lactoferrin protein standard.

3. Materials

The following materials are required to carry out the analysis.

3.1 Standards

Lactoferrin from bovine milk [L9507] - a purified protein standard with approximately 98% purity by HPLC is purchased from Sigma-Aldrich, Auckland, New Zealand.

3.2 Reagents

Water must be deionised (DI) and filtered through a 0.2 μm filter unit or of equivalent quality. Trifluoroacetic acid (TFA) with purity of ≥99% is used. Acetonitrile (CH_3CN) must be of HPLC or equivalent grade

3.3 Apparatus

- Analytical balance capable of weighing any sample mass to an accuracy of 0.0001g (four decimal places)
- HPLC/UPLC system equipped with a temperature controlled column oven, gradient system with an automatic sampler and UV-Vis detector recording at 220 nm
- Aeris™ 3.6 micron WIDEPORE XB-C8 200Å, LC Column 250 x 4.6 mm
- Cellulose acetate filters, 25 mm, 0.2 μm
- Micro-spin centrifugal filter units, 0.5 mL, 0.2 μm
- Amber HPLC vials

3.4 Method safety equipment

- Lab coats
- Nitrile free gloves
- Safety glasses
- Fume hood
- Breathing apparatus, if required

3.5 Mobile phase solvents

Solvent A: Deionised water containing 0.1% (v/v) TFA, dilute 1 mL of TFA in 999 mL DI water and filter through a 0.2 µm cellulose acetate filter unit

Solvent B: Acetonitrile containing 0.1% TFA (v/v), dilute 1 mL of TFA in 999 mL of HPLC grade acetonitrile

3.6 Lactoferrin standard preparation

A commercial LF protein standard stock is prepared as follows. An appropriate volume of phosphate buffer saline (PBS) is directly added to the LF vial of commercial protein to yield a final protein concentration of 10 mg/mL and mixed slowly for an hour at RT until the protein is completely dissolved. Protein stocks are filtered through a 0.2 micron centrifugal filter unit, divided into 50 µL aliquots (in low protein binding tubes), and stored at -20°C until the preparation of working concentrations. The LF protein standard stock is further diluted (10-fold) in HPLC solvent A to yield a final protein concentration of 1 mg/mL and serial dilutions (0 – 300 ng/µL) are prepared in the same solvent for generating calibration curves using HPLC system.

3.7 Liquid sample preparation

Liquid lactoferrin samples provided by the Client are prepared as follows. A stock LF solution is prepared by mixing 100 µL of liquid LF sample with 900 µL of DI water (10-fold dilution) and filtering the stock using a 0.2 micron centrifugal filter unit. A working concentration of LF for HPLC analysis is prepared by addition of 25 µL of the above stock to 975 µL of solvent A (400-fold final dilution, assuming that the protein content of liquid test samples are expected to be approximately 50 – 100 µg/mL). All prepared stocks (10-fold dilutions) are stored at -20°C for further use, if required.

3.8 Powder sample preparation

Powder lactoferrin samples provided by the Client are prepared as follows. A stock LF solution is prepared by accurately weighing approximately 50 mg of powdered sample into a 15 mL 'Falcon' tube, 4.95 mL of DI water is added to dissolve the

protein (10 mg/mL final). Sample tubes are kept on a horizontal shaker for an hour at RT to dissolve the protein completely.1 mL of the above stock solution above is transferred into a 1.5 mL microcentrifuge tube and spun-down for 5 minutes at 10000 rpm using a bench-top centrifuge to remove any undissolved particulate material in the sample. The supernatant from the above is filtered through a 0.2 micron centrifugal filter unit. A working stock of LF for HPLC analysis is prepared by addition of 25 µL of the above stock to 975 µL of solvent A (40-fold dilution of 10 mg/mL preparation). All stock preparations (10 mg/mL) are stored at -20°C for further use, if required.

4. References

Billakanti, J.M (2014). RP-HPLC method development for the estimation of lactoferrin purity. Callaghan Innovation reports – CIR-95.

5. Procedure applicability

This method is suitable for the determination of the LF content in both liquid and powder protein products prepared by cation exchange chromatography and containing various other basic milk proteins which commonly bind to cation exchange chromatography resins.

6. Instrument operation

Ensure the following operating conditions are set (See chromatography profile in the Appendix A and B)

Column: Aeris™ 3.6 micron WIDEPORE XB-C8 200Å, LC Column 250 x 4.6 mm (Phenomenex, New Zealand)

Detection wavelength: UV 220 nm

Mobile phases: Solvent A and Solvent B

Retention Time: Lactoferrin – 7.07±0.01 minutes

Injection volume: 25 µL

Flow rate: 1 mL/min

Column temperature: 30°C

Run time: 15 minutes

Mobile phase gradient: Table 1

Table 1: Mobile phase gradient profile for HPLC analysis of LF

Time (minutes)	% Solvent B
0.0	25
1.0	25
3.0	40
4.0	50
5.0	50
8.0	95
11.0	95
11.1	25
15.0	25

7. Determination of lactoferrin

- Program the mobile phase, set up the sequence table with sample details (minimum of triplicate injections for calibration standards with 25 µL of each injection) and save the method
- Prime the system and then equilibrate the column for 20 minutes
- Inject a blank sample with no protein (solvent A only)
- Inject samples (triplicate) containing known concentration of LF for comparison along with test samples
- When the sample run is complete (ensure the Shut Down program of the project is complete), wash the column with 65% acetonitrile (20 minutes) and store the column with 65% acetonitrile solvent system

Calculation of Lactoferrin, $\%LF = \frac{LF\ peak}{Sum\ of\ all\ peaks} \times 100$

Where, LF peak = Area of LF peak (peak at 7.07 minutes); Sum of all peaks = sum of all the areas of peaks in the chromatogram from 3 – 9 minutes

8. Quality control

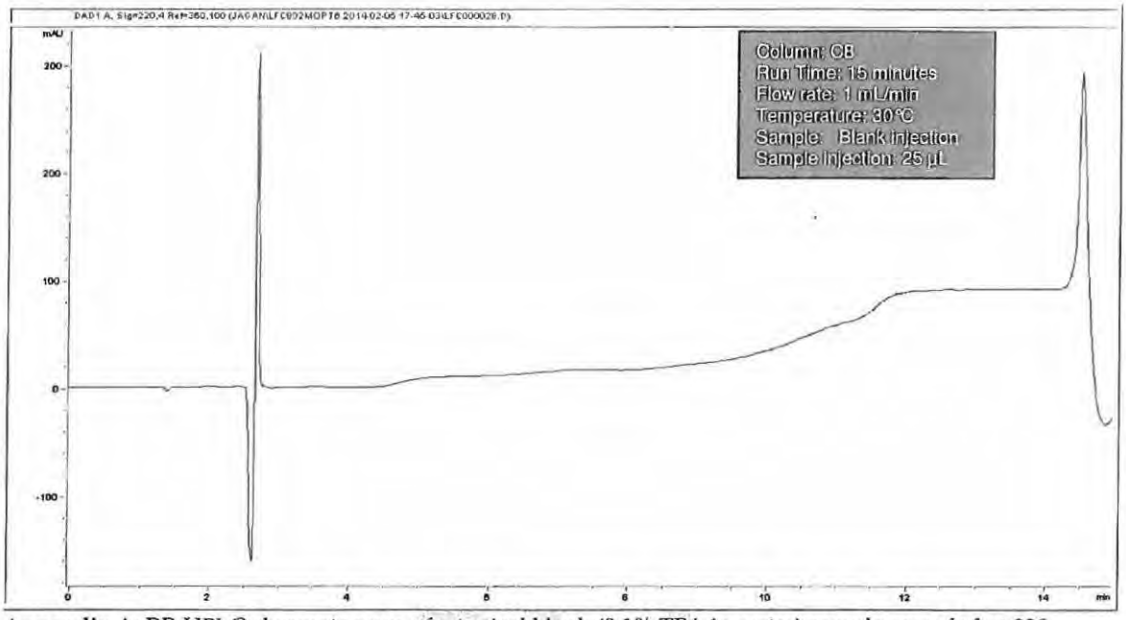
For each batch analysed, determine the purity of a commercial lactoferrin standard with known concentration and purity as a reference standard material. The percentage of recovery results shall be within the expected range.

9. Test report

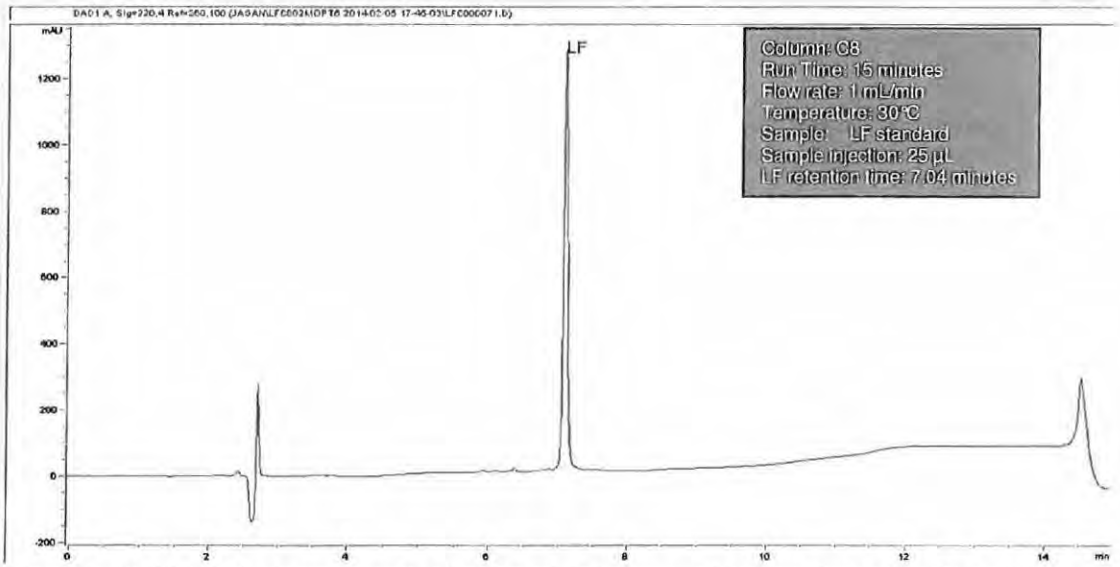
Report all results of lactoferrin (percentage of LF) to the nearest value (LF content in terms of %of protein) of one decimal place. As test method, mention "HPLC method" in the test reports.

10. Document control

Appendix



Appendix A: RP-HPLC chromatogram of a typical blank (0.1% TFA in water) sample recorded at 220 nm.



Appendix B: RP-HPLC chromatogram of a typical lactoferrin calibration standard (200 ng/µL) recorded at 220 nm.

SYNLAIT MILK THE COMMON SEAL OF LIMITED

Initiated by: Jagan M Billakanti
Approved By:

Date effective: 25-02-2014

Safety summary

See the relevant Material Safety Data Sheets (MSDS) for comprehensive information on the hazardous materials and the Laboratory Manual for spills and waste disposal procedures.

Chemical Hazards:

Substance	Hazardous	Potential Hazards and Dangers	Recommended Precautions
Acetonitrile	Yes	Highly flammable. Toxic by inhalation or swallowed. May cause irritation by contact to skin or eyes.	Avoid all ignition sources. Avoid inhaling and contact with skin or eyes. Use in a fume hood. Wear gloves when handling undiluted or concentrated solutions.
Trifluoroacetic acid	Yes	Corrosive. The substance is toxic to lungs, mucous membranes. May cause irritation by contact to skin or eyes.	Avoid inhaling and contact with skin or eyes. Use in a fume hood. Wear gloves when handling and preparing solvents.
Lactoferrin	No	None	

Process and Equipment Hazards:

Equipment	Potential Hazards and Dangers	Recommended Precautions
Centrifuge	Uncontrollable vibration	Ensure that the sample tubes are balanced before they placed in the centrifuge. Do not open the centrifuge cover until machine stops completely

Special First Aid Procedures: Record and report all incidents to management and seek immediate medical attention, if required.

Material	Recommended First Aid Procedures
Acetonitrile	Immediately flush eyes and skin with plenty of running water (cold water) for at least 15 minutes. Ingestion: If swallowed, do not induce vomiting unless directed to do so. Seek medical attention. (See MSDS for more details)
Trifluoroacetic acid	Immediately flush eyes and skin with plenty of running water (cold water) for at least 15 minutes. Do not use an eye ointment. Seek medical attention. Ingestion: If swallowed, do not induce vomiting unless directed to do so. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention. (See MSDS for more details)

MASTERSIZER 2000

Result Analysis Report

Sample Name:
LFN05210 #1610004027 - Average

Sample Source & type:
Synlait

Sample bulk lot ref:
test in ethanol

SOP Name:
SMP 1.52 (in ethanol)

Measured by:
cehall

Result Source:
Averaged

Measured:
Tuesday, 26 April 2016 11:58:27 a.m.

Analysed:
Tuesday, 26 April 2016 11:58:28 a.m.

Particle Name:
SMP powder

Particle RI:
1.520

Dispersant Name:
Ethanol

Accessory Name:
Hydro 2000S (A)

Absorption:
0.001

Dispersant RI:
1.360

Analysis model:
General purpose (spherical)

Size range:
0.020 to 2000.000 um

Weighted Residual:
0.409 %

Sensitivity:
Enhanced

Obscuration:
10.90 %

Result Emulation:
Off

Concentration:
0.0511 %Vol

Specific Surface Area:
0.18 m²/g

Span :
1.781

Surface Weighted Mean D[3,2]:
33.250 um

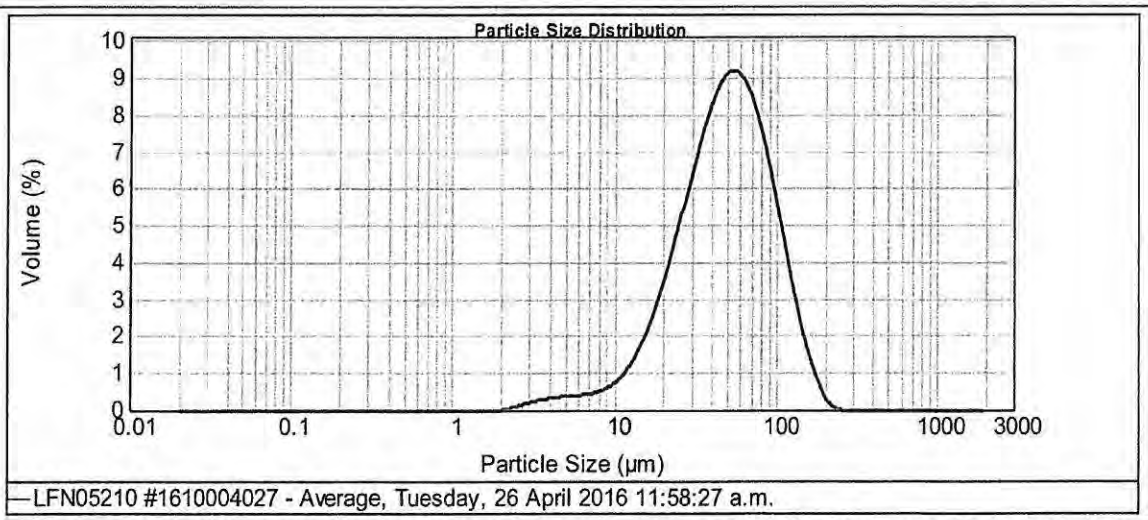
Uniformity:
0.553

Vol. Weighted Mean D[4,3]:
57.153 um

Result units:
Volume

---

d(0.1): 18.823 um **d(0.5):** 49.360 um **d(0.9):** 106.756 um



Size (µm)	Volume In %	Size (µm)	Volume In %	Size (µm)	Volume In %	Size (µm)	Volume In %	Size (µm)	Volume In %	Size (µm)	Volume In %
0.010	0.00	0.123	0.00	1.520	0.00	18.738	4.99	231.013	0.02	2848.036	0.00
0.012	0.00	0.152	0.00	1.874	0.02	23.101	7.06	284.804	0.00	3511.192	0.00
0.015	0.00	0.187	0.00	2.310	0.15	28.480	9.24	351.119	0.00	4328.761	0.00
0.019	0.00	0.231	0.00	2.848	0.31	35.112	11.14	432.876	0.00	5336.699	0.00
0.023	0.00	0.285	0.00	3.511	0.42	43.288	12.34	533.670	0.00	6579.332	0.00
0.028	0.00	0.351	0.00	4.329	0.49	53.367	12.46	657.933	0.00	8111.308	0.00
0.035	0.00	0.433	0.00	5.337	0.54	65.793	11.36	811.131	0.00	10000.000	0.00
0.043	0.00	0.534	0.00	6.579	0.62	81.113	9.19	1000.000	0.00		
0.053	0.00	0.658	0.00	8.111	0.81	100.000	6.45	1232.847	0.00		
0.066	0.00	0.811	0.00	10.000	1.24	123.285	3.77	1519.911	0.00		
0.081	0.00	1.000	0.00	12.328	2.03	151.991	1.69	1873.817	0.00		
0.100	0.00	1.233	0.00	15.199	3.27	187.382	0.39	2310.130	0.00		
0.123		1.520		18.738		231.013		2848.036			

Operator notes:

Morinaga Milk Industry Co. Ltd

Lactoferrin Specification as submitted in GRN 465 (2014)

MORINAGA MILK INDUSTRY CO., LTD.
33-1, SHIBA 5-CHOME, MINATO-KU, TOKYO 108-8384, JAPAN
TEL : 81-3-3798-0152
FAX : 81-3-3798-0107
E-mail: interntl@morinagamilk.co.jp

Free translation (summary) of specification for "Lactoferrin Concentration" in the existing food additives list in Japan

Definition :

Substance whose major content is lactoferrin derived from mammal milk.

Contents :

On dry matter basis, it should contain 14.0 – 16.5% of nitrogen (N=14.01). And in protein, more than 85% of lactoferrin should be contained.

Appearance :

Pink salmon color powder, no odor.

Confirmation test :

(1) When 1ml of sodium hydroxide solution and a drop of copper sulfate solution are added into 10 ml of lactoferrin solution and shaken, it brings about blue precipitation and color of solution turns to purple.

(2) When 1 ml of diluted hydrochloric acid is added into lactoferrin solution, the red color in the solution disappears.

Purity test :

(1) pH : 5.2 – 7.2 (1.0g, water 50ml)

(2) Iron content : not more than 0.050% as Fe. (Atomic absorption analysis)

(3) Heavy metals : not more than 20 μ g / g as Pb.

(4) Arsenic : not more than 4.0 μ g/ g as As_2O_3

Loss on drying : not more than 6.0% (105℃, 5 hours)

Residue on ignition : not more than 2.5%

Quantitative determination method :

(1) Nitrogen : Determines quantity of nitrogen Semimicro Kjeldahl method

(2) Lactoferrin in protein : HPLC

Make 50ml of test solution by dissolving 0.1g of lactoferrin into sodium chloride solution.

Measure 25 μ l test solution and do the HPLC test and determine lactoferrin contents by the following formula.

000175

MORINAGA MILK INDUSTRY CO., LTD.
TEL : 81-3-3798-0152
FAX : 81-3-3798-0107
33-1, SHIBA 5-CHOME, MINATO-KU, TOKYO 108-8384, JAPAN
E-mail: interntl@morinagamilk.co.jp

- Lactoferrin (%) = ALF / APK x 100
  - ALF : Main peak area (lactoferrin)
  - APK : Total peak area

- Operating condition
  - Detector : Ultra-Violet Absorbance Detector (Detection wavelength : 280nm)
  - Column packing material : Polyvinyl alcohol gel made by chemical binding of 5 μ g of butyl group.
  - Column : Stainless column of 4.6mm inner diameter and 15cm length.
  - Column temperature : 30 – 40 ℃
  - Mobile phase A : Acetonitrile / NaCl solution (1:9)
  - Mobile phase B : Acetonitrile / NaCl solution (1:1)
  - Concentration gradient : 30 minutes of linear gradient from A:B (50:50) to A:B (0:100)
  - Flow rate : Adjust so that the retention time of main peak would be about 10 minutes.

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Standard and Specification > Natural Additives > Lactoferrin Concentrates

Lactoferrin Concentrates

Definition This is obtained by concentrating milk that is previously defatted and purified by separation. The major component is lactoferrin. It also contains whey protein.

[Compositional Specifications of Lactoferrin Concentrates]

Content Lactoferrin Concentrates should contain not less than 90.0% of lactoferrin.

Description Lactoferrin Concentrates is scentless pale orange red~pale reddish brown powder.

Identification When Lactoferrin Concentrates is quantitatively analyzed, a lactoferrin peak is observed at 280 nm.

Purity

(1) Arsenic : 0.5 g of Lactoferrin Concentrates is placed in a platinum, quartz, or porcelain crucible. 10 ml of magnesium nitrate in ethyl alcohol (1→50) is added to the crucible and then alcohol is ignited. It is then reduced to ash by heating at 450~550°. If carbonaceous substance persists, it is wetted with minute amount of nitric acid, which is further heat treated at 450~550°. After cooling, 3 ml of hydrochloric acid is added to the residue, which is then dissolved by heating in a water bath. When test for arsenic is carried out with this test solution, it should not be more than 2ppm.

(2) Heavy Metals : 2 g of Lactoferrin Concentrates are carbonized by heating mildly in a quartz or porcelain crucible. After cooling, add 2 ml of nitric acid and 5 drops of sulfuric acid, it is heated until white smoke disappears, which is then reduced to ash by further heating at 450~550°. After cooling, 2 ml of hydrochloric acid is added, which is then evaporated to dryness in a water bath. 3 drops of hydrochloric acid and 10 ml of hot water are added to the resulting residue, which is then heated for 2 minutes. After cooling, 1 drop of phenolphthalein indicator solution is added, then ammonia solution is added until the color of the solution becomes pale red. The resulting solution is transferred into a Nestler cylinder by rinsing with water. 50 ml of test solution is prepared by adding 2 ml of diluted acetic acid (1→20) and water. When this solution tested for heavy metals, the content should not be more than 10ppm. Color standard solution is prepared by the following procedure. 2 ml of nitric acid, 5 drops of sulfuric acid, and 2 ml of hydrochloric acid are added and evaporated to dryness in a crucible that is made of the same material used for test solution preparation. 3 drops of hydrochloric acid are added to the residue, which is then transferred into another Nestler cylinder as described above. Finally, 2 ml of lead standard solution, 2 ml of diluted acetic acid (1→20), and water are added to bring the total volume to 50 ml.

(3) pH : pH of this solution (2→100) should be 5.2~7.2.

(4) Coliform Group : Lactoferrin Concentrates is tested by Microbe Test Methods for [Coliform Group] in General Test Methods in Food Code. It should contain 30 or less per 1 g of this product.

Residue on Ignition When thermogravimetric analysis is done with 1 g of Lactoferrin Concentrates, the amount of residue should not be more than 1.3%.

Assay

Approximately 20 mg of Lactoferrin Concentrates is accurately weighed and dissolved in 0.5 M of sodium chloride solution (total volume 10 ml). The solution is filtered through a 0.45 μm Millipore filter (Test Solution). Separately, a Standard Solution is prepared with 20 mg of lactoferrin standard following the same procedure. 20 μl each of Standard Solution and Test Solution is injected into liquid chromatograph and the content of lactoferrin is obtained from the following equation.

$$\text{Content (\%)} = \frac{Au \times Ws}{As \times Wu} \times 100$$

Au : Peak area of Test Solution
As : Peak area of Standard Solution
Ws : amount of standard material (mg)
Wu : amount of sample (mg)

[Operation Conditions]
- Detector : UV 280 nm
- Column : Ashaipak C4P 50(4.6 mm × 150 mm) or its equivalent
- Column Temperature : Room temperature
- Mobile Phase : Solution A: Solution B (30: 70)
  Solution A : acetonitrile: 0.5M sodium chloride solution (1: 9)
  Solution B : acetonitrile: 0.5M sodium chloride solution (5: 5)
  Solutions A, B contains 0.03% of Trifluoroacetic acid.
- Flow rate: 0.8 ml/min

TECHNICAL SPECIFICATION

ISO/TS 22964

IDF/RM 210

First edition
2006-02-01

Milk and milk products — Detection of *Enterobacter sakazakii*

*Lait et produits laitiers — Détection de l'*Enterobacter sakazakii

Reference numbers
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IDF/RM 210:2006(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TS 22964|IDF/RM 210 was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 5, *Milk and milk products*, and the International Dairy Federation (IDF). It is being published jointly by ISO and IDF.

Foreword

IDF (the International Dairy Federation) is a worldwide federation of the dairy sector with a National Committee in every member country. Every National Committee has the right to be represented on the IDF Standing Committees carrying out the technical work. IDF collaborates with ISO in the development of standard methods of analysis and sampling for milk and milk products.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the Action Teams and Standing Committees are circulated to the National Committees for voting. Publication as an International Standard requires approval by at least 50 % of IDF National Committees casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a Standing Committee may decide to publish another type of normative document which is called by IDF: *Reviewed method*. Such a method represents an agreement between the members of a Standing Committee and is accepted for publication if it is approved by at least 50 % of the committee members casting a vote. A *Reviewed method* is equal to an ISO/PAS or ISO/TS and will, therefore, also be published jointly under ISO conditions.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. IDF shall not be held responsible for identifying any or all such patent rights.

ISO/TS 22964|IDF/RM 210 was prepared by the International Dairy Federation (IDF) and Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 5, *Milk and milk products*. It is being published jointly by IDF and ISO.

All work was carried out by the Joint ISO-IDF Action Team on *Harmonization*, of the Standing Committee on *Microbiological methods of analysis*, under the aegis of its project leaders, Mr D.J.C. van den Berg (NL) and Mr H. Joosten (CH).

Milk and milk products — Detection of *Enterobacter sakazakii*

1 Scope

This Technical Specification specifies a method for the detection of *Enterobacter sakazakii* in milk powder and powdered infant formula.

The method is also applicable to environmental samples collected from milk powder or infant formula factories.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8261|IDF 122, *Milk and milk products — General guidance for the preparation of test samples, initial suspensions and decimal dilutions for microbiological examination*

ISO 7218, *Microbiology of food and animal feeding stuffs — General requirements and guidance for microbiological examinations*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
presumptive *Enterobacter sakazakii*
microorganisms which form typical colonies on a chromogenic isolation agar, when tests are carried out in accordance with this Technical Specification

3.2
Enterobacter sakazakii
microorganisms which form typical colonies on a chromogenic isolation agar, form yellow colonies on tryptone soya agar and display biochemical characteristics as described, when tests are carried out in accordance with this Technical Specification

4 Principle (see also annex A)

4.1 Pre-enrichment in non-selective liquid medium

The pre-enrichment medium is inoculated with the test portion and incubated at 37 °C ± 1 °C for 16 h to 20 h.

4.2 Enrichment in selective liquid medium

The selective enrichment medium is inoculated with the culture obtained in 4.1 and incubated at 44 °C ± 0,5 °C for 22 h to 26 h.

4.3 Plating out and identification

A chromogenic agar is inoculated with the enrichment culture obtained in 4.2 and incubated at 44 °C ± 1 °C for 22 h to 26 h.

4.4 Confirmation

Typical colonies are selected from the chromogenic agar, and isolates producing a yellow pigment on tryptone soya agar are biochemically characterized.

5 Culture media and reagents

5.1 General

Use only reagents of recognized analytical grade, unless otherwise specified, and distilled or demineralized water or water of equivalent purity. The water shall be free from substances that might inhibit the growth of microorganisms under the test conditions specified in this Technical Specification. See also ISO 6887-1 and ISO 8261|IDF 122.

In order to improve the reproducibility of the results, it is recommended that, for the preparation of culture media, dehydrated basic components or dehydrated complete media be used. In that case, follow the manufacturer's instructions rigorously. See also ISO 6887-1.

The pH values given refer to a temperature of 25 °C. Adjustments, if necessary, are made by adding either hydrochloric acid [c(HCl) = 1 mol/l] or sodium hydroxide solution [c(NaOH) = 1 mol/l].

If not used immediately, store the prepared culture media and reagents under conditions that do not produce any change in their composition, in the dark at a temperature between 0 °C and 5 °C, for no longer than 1 month, unless otherwise stated.

5.2 Culture media

5.2.1 Buffered peptone water (BPW)

5.2.1.1 Composition

Enzymatic digest of casein	10,0 g
Sodium chloride (NaCl)	5,0 g
Disodium hydrogen phosphate dodecahydrate ($Na_2HPO_4 \cdot 12\ H_2O$)	9,0 g
Potassium dihydrogen phosphate (KH_2PO_4)	1,5 g
Water	1 000 ml

5.2.1.2 Preparation

Dissolve each of the components in the water, by heating if necessary. Adjust the pH, if necessary, to 7,0 ± 0,2 at 25 °C. Distribute the BPW in flasks or tubes according to the analytical needs. Sterilize at 121 °C for 15 min.

5.2.2 Modified lauryl sulfate tryptose broth (mLST)/vancomycin medium

5.2.2.1 Modified lauryl sulfate tryptose broth (mLST)

5.2.2.1.1 Composition

Sodium chloride (NaCl)	34,0 g
Enzymatic digest of animal and plant tissue	20,0 g
Lactose ($C_{12}H_{22}O_{11}$)	5,0 g
Potassium dihydrogen phosphate (KH_2PO_4)	2,75 g
Dipotassium hydrogen phosphate (K_2HPO_4)	2,75 g
Sodium lauryl sulfate ($C_{12}H_{25}NaO_5S$)	0,1 g
Water	1 000 ml

5.2.2.1.2 Preparation

Dissolve each of the components in the water, by heating if necessary.

Adjust the pH, if necessary, to $6,8 \pm 0,2$ at 25 °C. Dispense 10 ml of mLST into tubes of dimensions 18 mm × 160 mm.

Sterilize the tubes at 121 °C for 15 min.

5.2.2.2 Vancomycin solution

5.2.2.2.1 Composition

Vancomycin	10 mg
Water	10 ml

5.2.2.2.2 Preparation

Dissolve the vancomycin in the distilled water. Mix and sterilize by filtration.

The vancomycin solution may be kept at 0 °C to 5 °C for 15 days.

5.2.2.3 mLST/vancomycin medium

Add 0,1 ml of vancomycin solution (5.2.2.2.2) to 10 ml of mLST solution (5.2.2.1.2) so as to obtain a final vancomycin concentration of 10 µg per millilitre of mLST.

The complete mLST/vancomycin medium may be kept at 0 °C to 5 °C for 1 day.

5.2.3 *Enterobacter sakazakii* isolation agar (ESIA™)[1)]

5.2.3.1 Composition

Pancreatic peptone of casein	7,0 g
Yeast extract	3,0 g
Sodium choride (NaCl)	5,0 g
Sodium desoxycholate	0,6 g
5-Bromo-4-chloro-3-indolyl α-D-glucopyranoside ($C_{14}H_{15}BrClNO_6$)	0,15 g
Crystal violet	2 mg
Agar	12,0 g to18,0 g[a]
Water	1 000 ml
[a] Depending on the gel strength of the agar.	

5.2.3.2 Preparation

Dissolve each of the components in the water by boiling. Adjust the pH, if necessary, to 7,0 ± 0,2 at 25 °C. Sterilize at 121 °C for 15 min.

Cool to between 44 °C and 47 °C. Pour about 15 ml of ESIA™ medium into sterile empty Petri dishes and allow to solidify on a cool even surface.

The medium may be kept at 0 °C to 5 °C for up to 14 days.

5.2.4 Tryptone soya agar (TSA)

5.2.4.1 Composition

Enzymatic digest of casein	15,0 g
Enzymatic digest of soya	5,0 g
Sodium chloride (NaCl)	5,0 g
Agar	9,0 g to 18,0 g[a]
Water	1 000 ml
[a] Depending on the gel strength of the agar.	

5.2.4.2 Preparation

Dissolve each of the components in the water by boiling. Adjust the pH, if necessary, to 7,3 ± 0,2 at 25 °C. Sterilize at 121 °C for 15 min. Cool to between 44 °C and 47 °C. Pour about 15 ml of TSA into sterile empty Petri dishes and allow to solidify on a cool even surface.

1) ESIA™ is the trade name of a product supplied by AES Laboratoire, Rue Maryse Bastié, Ker Lann, F-35172 Bruz (FR) . This information is given for the convenience of users of this Technical Specification|IDF Reviewed Method and does not constitute an endorsement by either ISO or IDF of the product named. Equivalent products may be used if they can be shown to lead to the same results.

5.2.5 Media and reagents for biochemical characterization

5.2.5.1 Reagent for detection of oxidase

5.2.5.1.1 Composition

N,N,N',N'-Tetramethyl-*p*-phenylenediamine dihydrochloride ($C_{10}H_{16}N_2 \cdot 2HCl$)	1,0 g
Water	100 ml

5.2.5.1.2 Preparation

Dissolve the component in the water immediately before use.

5.2.5.2 L-Lysine decarboxylation medium

5.2.5.2.1 Composition

L-Lysine monohydrochloride ($C_6H_{14}N_2O_2 \cdot HCl$)	5,0 g
Yeast extract	3,0 g
Glucose ($C_6H_{12}O_6$)	1,0 g
Bromocresol purple	0,015 g
Water	1 000 ml

5.2.5.2.2 Preparation

Dissolve each of the components in the water, by heating if necessary. Adjust the pH, if necessary, so that after sterilization it is 6,8 ± 0,2 at 25 °C. Dispense 5 ml of L-lysine decarboxylation medium into tubes of dimensions 18 mm × 160 mm.

Sterilize the tubes at 121 °C for 15 min.

5.2.5.3 L-Ornithine decarboxylation medium

5.2.5.3.1 Composition

L-Ornithine monohydrochloride ($C_5H_{12}N_2O_2 \cdot HCl$)	5,0 g
Yeast extract	3,0 g
Glucose ($C_6H_{12}O_6$)	1,0 g
Bromocresol purple	0,015 g
Water	1 000 ml

5.2.5.3.2 Preparation

Dissolve each of the components in the water, by heating if necessary. Adjust the pH, if necessary, so that after sterilization it is 6,8 ± 0,2 at 25 °C.

Dispense 5 ml of L-ornithine decarboxylation medium into tubes of dimensions 18 mm × 160 mm. Sterilize the tubes at 121 °C for 15 min.

5.2.5.4 L-Arginine dihydrolation medium

5.2.5.4.1 Composition

L-Arginine monohydrochloride ($C_6H_{14}N_4O_2 \cdot HCl$)	5,0 g
Yeast extract	3,0 g
Glucose ($C_6H_{12}O_6$)	1,0 g
Bromocresol purple	0,015 g
Water	1 000 ml

5.2.5.4.2 Preparation

Dissolve each of the components in the water, by heating if necessary. Adjust the pH, if necessary, so that after sterilization it is 6,8 ± 0,2 at 25 °C.

Dispense 5 ml of L-arginine dihydrolation medium into tubes of dimensions 18 mm × 160 mm. Sterilize the tubes at 121 °C for 15 min.

5.2.5.5 Media for fermentation of carbohydrates (peptone water with phenol red, D-sorbitol, L-rhamnose, D-sucrose, D-melibiose and amygdaline)

5.2.5.5.1 Basic medium

5.2.5.5.1.1 Composition

Enzymatic digest of casein	10 g
Sodium chloride (NaCl)	5 g
Phenol red	0,02 g
Water	1 000 ml

5.2.5.5.1.2 Preparation

Dissolve each of the components in the water, by heating if needed. Adjust the pH, if necessary, so that after sterilization it is 6,8 ± 0,2 at 25 °C.

Dispense the basic medium into flasks of suitable capacity. Sterilize at 121 °C for 15 min.

5.2.5.5.2 Carbohydrate solutions (D-sorbitol, L-rhamnose, D-sucrose, D-melibiose or amygdaline), 80 mg/ml

5.2.5.5.2.1 Composition

Carbohydrate	8 g
Water	100 ml

5.2.5.5.2.2 Preparation

Dissolve separately each of the four carbohydrate components in the water so as to obtain four carbohydrate solutions. Sterilize all by filtration.

5.2.5.5.3 Complete carbohydrate fermentation mediums

5.2.5.5.3.1 Composition

Basic medium (5.2.5.5.1)	875 ml
Carbohydrate solution (5.2.5.5.2)	125 ml

5.2.5.5.3.2 Preparation

For each carbohydrate, add the prepared carbohydrate solution (5.2.5.5.2) aseptically to basic medium (5.2.5.5.1) and mix. Dispense 10 ml of complete medium of each carbohydrate aseptically into tubes of dimensions 18 mm × 160 mm.

5.2.5.6 Simmons citrate medium

5.2.5.6.1 Composition

Sodium citrate ($Na_3C_6H_5O_7$)	2,0 g
Sodium chloride (NaCl)	5,0 g
Dipotassium hydrogen phosphate (K_2HPO_4)	1,0 g
Ammonium dihydrogen phosphate ($NH_4H_2PO_4$)	1,0 g
Magnesium sulfate ($MgSO_4$)	0,2 g
Bromothymol blue	0,08 g
Agar	8,0 g to 18,0 g[a]
Water	1 000 ml

[a] Depending on the gel strength of the agar.

5.2.5.6.2 Preparation

Dissolve each of the components or the dehydrated complete medium in the water by boiling. Adjust the pH, if necessary, so that after sterilization it is 6,8 ± 0,2 at 25 °C.

Dispense 10 ml of Simmons citrate medium into tubes (6.7) of dimensions 18 mm × 160 mm. Sterilize the tubes at 121 °C for 15 min.

Let the tubes stand in a tilted position so as to obtain a butt 2,5 cm deep.

6 Apparatus and glassware

Disposable glassware is an acceptable alternative to reusable glassware, provided that it has suitable specifications.

Usual microbiological laboratory equipment and, in particular, the following:

6.1 Apparatus for dry sterilization (oven) or **wet sterilization** (autoclave)

See ISO 7218.

6.2 Total delivery pipettes, having a nominal capacity of 1 ml.

6.3 Water bath, capable of being maintained at 44 °C ± 0,5 °C.

6.4 Petri dishes, made of glass or plastic, of diameter 90 mm to 100 mm.

6.5 Incubators, capable of operating at 25 °C ± 1 °C, 30 °C ± 1 °C and 44 °C ± 1 °C, respectively.

6.6 Loop, made of platinum-iridium or nickel chromium, of diameter approximately 3 mm, or disposable loops.

6.7 Test tubes, of diameter 18 mm and length 160 mm (plugged or with screw caps).

6.8 pH meter, accurate to 0,1 pH unit at 25 °C ± 1 °C.

7 Sampling

It is important that the laboratory receive a sample which is truly representative and has not been damaged or changed during transport or storage.

Sampling is not part of the method specified in this Technical Specification. A recommended sampling method is given in ISO 707|IDF 50.

8 Preparation of test sample

Prepare test samples in accordance with ISO 8261|IDF 122.

9 Procedure (see the scheme in Annex A)

9.1 Test portion

To prepare the primary dilution, add x g of the test sample (Clause 8) to 9 times x ml of pre-enrichment medium (5.2), which is the ratio of test sample to pre-enrichment medium specified in this method.

Allow dry samples to disperse in the liquid without stirring. If a sample has not been dissolved completely after 30 min, than mix it gently with the medium.

9.2 Pre-enrichment

Incubate the inoculated pre-enrichment medium (9.1) at 37 °C ± 1 °C for 18 h ± 2 h.

9.3 Selective enrichment

After incubation of the inoculated pre-enrichment medium, transfer 0,1 ml of the obtained culture (9.2) into 10 ml of mLST/vancomycin medium (5.2.2.3). Incubate at 44 °C ± 0,5 °C for 24 h ± 2 h.

It is recommended to use either a water bath (6.3) or a forced-air incubator to ensure that the maximum temperature (44,5 °C) is not exceeded.

9.4 Isolation of presumptive *Enterobacter sakazakii*

After incubation of the inoculated mLST/vancomycin medium (9.3), streak a loopful (*ca.* 10 µl) onto the surface of the *Enterobacter sakazakii* isolation agar plate (5.2.3.2). Incubate the plate at 44 °C ± 1 °C for 24 h ± 2 h.

After incubation, examine the chromogenic plate for the presence of typical colonies of presumptive *Enterobacter sakazakii*.

NOTE Typical colonies are small to medium sized (1 mm to 3 mm) green to blue-green colonies. Non-typical colonies are often slightly transparent and violet coloured.

9.5 Confirmation

9.5.1 Production of a yellow pigment

9.5.1.1 Selection of colonies

Select one to five of the typical colonies of presumptive *Enterobacter sakazakii* examined on the incubated chromogenic plate (9.4).

9.5.1.2 Incubation

Streak the selected colonies (9.5.1.1) onto the surface of the TSA plate (5.2.4.2) so that after incubation separate colonies can be observed. Incubate the plate at 25 °C ± 1 °C for 44 h to 48 h. After incubation, examine the TSA plates for the presence of yellow-pigmented colonies.

When only one colony is selected (9.5.1.1) and transferred to the TSA plate and after incubation no yellow-pigmented colonies can be seen, select four more typical colonies (9.5.1.1) and proceed according to 9.5.1.2. If there are fewer than five typical colonies, select all of them.

CAUTION — Some exceptional strains of *Enterobacter sakazakii* might not form a yellow pigment under the test conditions specified in this Technical Specification, or the pigment is lost due to sub-culturing. In such cases using this method might, therefore, overlook such strains.

9.5.2 Biochemical confirmation

9.5.2.1 General

Miniaturized biochemical identification kits, currently available commercially and permitting the identification of *Enterobacter sakazakii*, may be used.

9.5.2.2 Selection of colonies

Select one yellow pigmented colony from each tryptone soya agar plate (9.5.1.2) for further biochemical characterization according to 9.5.2.3 to 9.5.2.8.

9.5.2.3 Oxidase

Using a glass rod or disposable inoculation needle, take a portion of each selected characteristic colony (9.5.2.2).

Streak the taken portion on a filter paper moistened with the oxidase reagent (5.2.5.1) or on a commercially available disc. Do not use a nickel/chromium loop or wire.

Consider the test to be negative when the colour of the filter paper has not changed to mauve, violet or deep blue within 10 s.

9.5.2.4 L-Lysine decarboxylase

Using a loop, wire or glass rod, inoculate the L-lysine decarboxylation medium (5.2.5.2) with each of the selected colonies (9.5.2.2) just below the surface of the liquid medium. Incubate the tubes at 30 °C ± 1 °C for 24 h ± 2 h.

A violet colour after incubation indicates a positive reaction. A yellow colour indicates a negative reaction.

9.5.2.5 L-Ornithine decarboxylase

Using a loop, wire or glass rod, inoculate the L-ornithine decarboxylation medium (5.2.5.3) with each of the selected colonies (9.5.2.2) just below the surface of the liquid medium. Incubate the tubes at 30 °C ± 1 °C for 24 h ± 2 h.

A violet colour after incubation indicates a positive reaction. A yellow colour indicates a negative reaction.

9.5.2.6 L-Arginine dihydrolase

Using a loop, wire or glass rod, inoculate the L-arginine dihydrolation medium (5.2.5.4) with each of the selected colonies (9.5.2.2) just below the surface of the liquid medium. Incubate the tubes at 30 °C ± 1 °C for 24 h ± 2 h.

A violet colour after incubation indicates a positive reaction. A yellow colour indicates a negative reaction

9.5.2.7 Fermentation of various sugars

Using a loop, wire or glass rod, inoculate each carbohydrate fermentation medium (5.2.5.5.3) with each of the selected colonies (9.5.2.2) just below the surface of the liquid medium. Incubate the tubes at 30 °C ± 1 °C for 24 h ± 2 h.

A yellow colour after incubation indicates a positive reaction. A red colour indicates a negative reaction.

9.5.2.8 Utilization of citrate

Using a loop, wire or glass rod, streak the selected colonies (9.5.2.2) onto the slant surface of Simmons citrate medium (5.2.5.6). Incubate the tubes at 30 °C ± 1 °C for 24 h ± 2 h.

The reaction is positive if the medium turns blue.

9.6 Interpretation of the results of the confirmation tests

Interpret the results according to Table 1.

Table 1 – Interpretation of results

Confirmatory test	Positive or negative reaction	Percent of *Enterobacter sakazakii* strains showing the reaction
Production of a yellow pigment	+	>99
Oxidase	–	>99
L-Lysine decarboxylase	–	>99
L-Ornithine decarboxylase	+	±90
L-Arginine dihydrolase	+	>99
Acid from		
— fermentation of D-sorbitol	–	±95
— fermentation of L-rhamnose	+	>99
— fermentation of D-sucrose	+	>99
— fermentation of D-melibiose	+	>99
— fermentation of amygdaline	+	>99
— hydrolysis of citrate	+	>95

10 Control cultures

In order to check the ability of the enrichment and isolation media to support the growth of *Enterobacter sakazakii*, introduce a low level inoculum of a reference culture of a recently isolated *Enterobacter sakazakii* strain, or of a reference strain from a recognized culture collection centre, into control flasks of the pre-enrichment medium (9.2). Proceed with this control flask as for the test cultures to demonstrate that the positive control culture is recovered.

11 Expression of results

In accordance with the interpretation of the test results (9.4), report the presence or absence of presumptive *Enterobacter sakazakii* in the test portion. In this case, no confirmation of the presumptive *Enterobacter sakazakii* found on the chromogenic plate has been carried out.

After confirmation by the procedure described in 9.5, of one or more of the presumptive *Enterobacter sakazakii* obtained in 9.4, report the presence or absence of *Enterobacter sakazakii* in the test portion.

Specify the final test result per mass (in grams) or per volume (in millilitres) of the analysed test sample.

12 Test report

The test report shall specify:

a) all information necessary for the complete identification of the sample;

b) the sampling method used, if known;

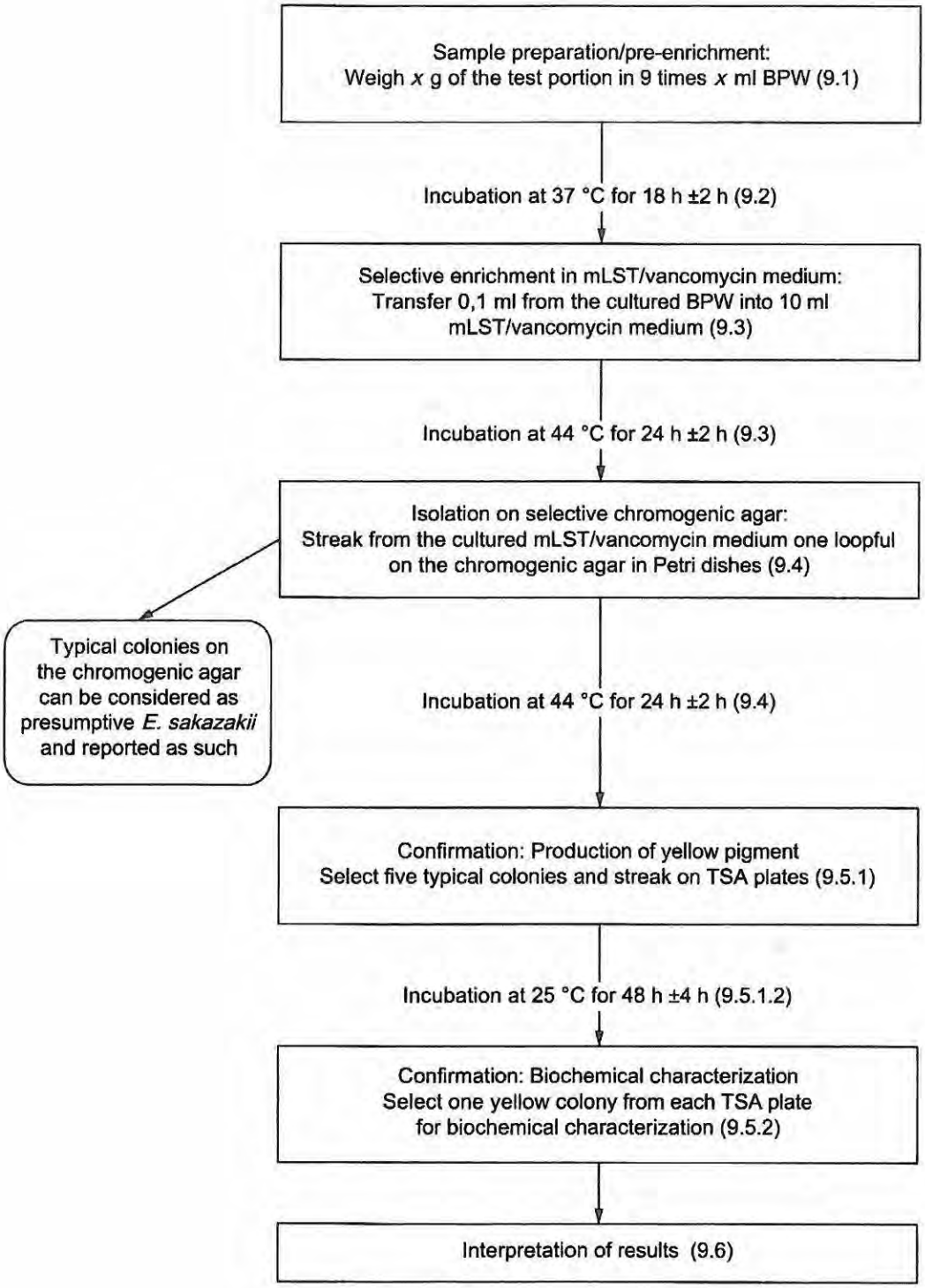
c) the test method used, with reference to this Technical Specification;

d) all operating details not specified in this Technical Specification, or regarded as optional, together with details of all incidents which may have influenced the result(s);

e) the test result(s) obtained.

Annex A
(informative)

Method flow scheme



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[1] ISO 707|IDF 50, *Milk and milk products — Guidance on sampling*

[2] ISO 6887-1, *Microbiology of food and animal feeding stuffs — Preparation of test samples, initial suspension and decimal dilutions for microbiological examination — Part 1: General rules for the preparation of the initial suspension and decimal dilutions*

[3] ISO/TS 11133-1, *Microbiology of food and animal feeding stuffs — Guidelines on preparation and production of culture media — Part 1: General guidelines on quality assurance for the preparation of culture media in the laboratory*

[4] GUILLAUME-GENTIL, O., SONNARD, V., KANDHAI, M.C., MARUGG, J.D. and JOOSTEN, H. A Simple and Rapid Cultural Method for Detection of *Enterobacter sakazakii* in Environmental Samples. *Journal of Food Protection*, **68**(1), 2005, pp. 64-69

APPENDIX 3, MONTHLY WATER SAMPLING

Document No: QUA-20192
Version: 18
Date: 25 March 2015
Page: 1 of 2

Month of _____

Week	Test Site	Comments	Date/Sampler
Week 1	Bore1 & Bore 2, x 3 samples each Bore Pump House x 2 Samples Domestic water UF water x2 Cow waterx3 B&C 1 & 2 D3 #1-4 TBC		
Week 2	Chilled water Hose HS21 Hose USHO0343 Hose U2HO0345 UF water D3 #1-4 TBC		
Week 3	Bore1 & Bore 2, x 3 samples each Bore Pump House x 2 Samples Domestic water UF water x2 Cow water x3 D3 #1-4 TBC		
Week 4	Hose USHO0348 Hose HS1 UF water Bore 1 & 2 turbidity (1 each) D3 #1-4 TBC		

Prepared by:	(b) (6)	Date:	23/3/2015
Authorised by:		Date:	25/03/2015
Quality:		Date:	25/3/2015

Test Site	Test Frequency	Test For	Standard	Testing By	Responsibilty
Bore water from main feed lines into storage tanks (Bore 1, Bore 2 & Bore 3)	Annual	Chemicals and heavy metals	Refer table 2.2 NZDWS	ELS Ltd	Quality
	Fortnightly	E.coli	<1/100ml	External lab	Quality
	Fornightly	Total viable count	Record only	External lab	Quality
	Fortnightly	Nitrate/ Nitrite	Record only	External lab	Quality
	Monthly	Turbidity	≤1 NTU	External lab	Quality
	Daily	Turbidity	≤1 NTU	Energy Centre operators	Energy Centre
Treated water from bore pump house after chlorination	Fortnighly	E.coli	<1/100ml	External lab	Quality
	Fortnighly	Nitrate/ Nitrite	Record only	External lab	Quality
	Daily	Chlorine	<5ppm	Process staff	Production staff
Hose HS21	Monthly	E.coli	<1/100ml	External lab	Quality
Hose HS1	Monthly	E.coli	<1/100ml	External lab	Quality
Hose USHO0343	Monthly	E.coli	<1/100ml	External lab	Quality
Hose U2HO0345	Monthly	E.coli	<1/100ml	External lab	Quality
Hose USHO0348	Monthly	E.coli	<1/100ml	External lab	Quality
SMD treated water (TW)	6 Monthly	Bacterial Endotoxin	<0.25EU/ml	ELS Ltd	Quality
Condensate ex clean-steam generator	Monthly	E.coli	<1/100ml	External lab	Quality
B&C 1	Monthly	E.coli	<1/100ml	External lab	Quality
B&C 2	Monthly	E.coli	<1/100ml	External lab	Quality
Chilled water	Monthly	E.coli	<1/100ml	External lab	Quality
UF Water (batch UF or MPD UF)	Fortnightly (take samples only when UF plant is in operation)	E.coli	<1/100ml	External lab	Quality
	Weekly (take samples only when UF plant is in operation)	UV Transmittance	> 80 percent cm^{-1}	External lab	Quality
	6 Monthly	Bacterial Endotoxin	<0.25EU/ml	ELS Ltd	Quality
Domestic water	Fortnightly	E.coli	<1/100ml	External lab	Quality
Steam condensate	Annual	FeO	Record only	External lab	Quality
	Annual	Fe2O3	Record only	External lab	Quality
	Annual	NaOH	Record only	External lab	Quality
	Annual	HNO3	Record only	External lab	Quality
	Annual	Taste	Record only	Quality	Quality
Cow Water	Fortnightly	E.coli	<1/100ml	External lab	Quality
	Fornightly	Total viable count	Record only	External lab	Quality
	Fortnightly	Nitrate/ Nitrite	Record only	External lab	Quality

Treated water - Point of Use:

Code (as per map)	Location
USHO0343	SMD Wet process
U2HO0345	Dryer 2 Wet process RL32
USHO0348	Dryer 2 Goss room
HS-1 A1HO8306	AMF Wet process
HS -21	Dryer 1 Wet process
B&C 1	Ground floor Wet Wash Room
B&C 2	Level 1 critical change room
TW SMD	Aseptic Storage Hose

Code (as per map)	Location
Domestic water	Energy centre café/main office café
Steam condensate	Boiler house
Cow water	D1 wet process/ tanker bay silos
D3 #1 TBC	Dryer 3 Concentrate Room
D3 #2 TBC	Dryer 3 Wet Wash Room
D3 #3 TBC	Dryer 3 Evap Hall
D3 #4 TBC	Dryer 3 Lactose Almix

PART 7:
APPENDIX 4: International Regulations

The information presented within Appendix 4 is **generally available** other than :
The Certified Translation of the Draft Chinese Standard for Lactoferrin (pages A4: 10 to A4: 19
and,
The Certified Translation of the Preparation Notes for the Draft Chinese Standard for Lactoferrin (pages A4: 20 to A4: 26)
which are **not generally available**.

http://www.usp.org/food-ingredients/development-process/priority-new-food-ingredient-monographs

Pages 000199-000255 have been removed in accordance with copyright laws. The removed reference citations are:

Commission Implementing Decision (EU) 2015/568 of 7 April 2015 amending Annex I to Implementing Decision 2012/725/EU as regards the definition of bovine lactoferrin (notified under document C(2015) 2173)
OJ L 93, 9.4.2015, p. 71–71 (BG, ES, CS, DA, DE, ET, EL, EN, FR, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV)
ELI: http://data.europa.eu/eli/dec_impl/2015/568/oj

National Standard of the People's Republic Of China, GB 14880-2012 National Food Safety Standard Standards for Uses of Nutritional Fortification Substances in Foods, https://chemlinked.com/regulatory-database/gb-14880-2012-national-food-safety-standard-standards-uses-nutritional-fortification-substances-foods

KFDA - Korea Food Additives Code 6/05/16, 3:27 PM, Standards for Manufacturing and Preparation >General Standards for Food Additive use in Foods,
http://fa.kfda.go.kr/standard/egongjeon_ilbansayong.jsp

SINGAPORE

CONSULTATION ON DRAFT FOOD (AMENDMENT) REGULATIONS 2015
(Pages 1 and 2 only)

Aim

The Agri-Food and Veterinary Authority (AVA) is seeking feedback from the food industry (local food manufacturers and importers) on the draft Food (Amendment) Regulations 2015.

Summary of amendments

The draft Food (Amendment) Regulations 2015 contains trade facilitating measures such as the provision for the use of advantame, a new sweetening agent, in foods under good manufacturing practice, as well as allowing bovine lactoferrin, a new ingredient, in infant formulas, at levels up to 100 mg/100 ml.

The amendments include a requirement that food products labelled as "organic" (or similar terms) must be certified as organic under an inspection and certification system that complies with the Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods, GL 32-1999; or equivalent.

"Veterinary drugs" will be included under the definition for "Incidental constituents" under Regulation 29. In conjunction with this amendment, a definition for "veterinary drugs" (based on Codex definition) will be included in the Food Regulations.

Other changes include the prohibition of the import, sale and advertisement of raw milk for direct human consumption; and provision for the use of the generic term "Modified Starches" for labelling purposes. Editorial amendments will be made to Regulations 9, 12, 30(3) and 38, to update the terms used, as well as to spell out the provisions in a clearer manner.

A detailed description on the proposed changes can be found in ANNEX I.

Request for comments

AVA invites views and comments on the draft Food (Amendment) Regulations 2015. All submissions should be clearly and concisely written, and should provide a reasoned explanation for any proposed revisions.

Submissions should reach AVA no later than 12:00 p.m., 21 December 2015, through mail, or email, to the following addresses:

Mail:
Regulatory Programmes Department
Agri-Food and Veterinary Authority
52 Jurong Gateway Road #14-01
Singapore 608550
Tel: +(65) 6805 2910
Fax: +(65) 6334 1831

(Attention: Mr Cheng Chee Seng)

Email:
cheng_chee_seng@ava.gov.sg

ANNEX - PROPOSED AMENDMENTS TO THE FOOD REGULATIONS

The Agri-Food and Veterinary Authority of Singapore (AVA) has completed a review of the Food Regulations and proposes the following amendments:

(A) TO ALLOW THE USE OF NEW FOOD ADDITIVE AND INGREDIENT

Advantame, a sweetening agent, will be permitted for use in food under good manufacturing practice. The safety of advantame has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and it is currently permitted for use as a sweetening agent in Australia, New Zealand, the European Union, Japan and the United States.

Due to advantame's intense sweetness (20,000 – 37,000 times sweeter than sucrose), use levels in food are low and self-limiting. Hence, there will not be a need to specify maximum use levels for advantame, and its usage will be governed by good manufacturing practice.

Bovine lactoferrin will be permitted for use in infant formula, at levels not exceeding 100 mg/100ml. Lactoferrin is a naturally occurring glycoprotein (complex oligosaccharide chains attached to polypeptide side chains) in milk. Because cow's milk contains approximately 10 times less lactoferrin as compared to human milk, addition of bovine lactoferrin to infant formula aims to emulate levels present in human breast milk.

Bovine lactoferrin has been allowed for use in infant formula in the EU, Japan, and the US. The proposed maximum level (100mg/100ml) is consistent with the level reported in the relevant EU legislation, as well as levels known to be used in the US.

(B) REQUIREMENT FOR CERTIFICATION FOR ORGANIC FOOD

In order to ensure that food products marketed as "organic" are indeed produced in a manner consistent with internationally accepted practice, AVA has been advising the food industry that they have to ensure that the food is certified as organically produced by the official certifying body for organic certification, which adopts the Codex Alimentarius Commission standards (or other similar standards) for organic food.

In this set of amendments, AVA proposes to include our advice to the industry in the Food Regulations, by incorporating a new provision that "organic food" must be certified under an inspection and certification system that complies with the Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999), or equivalent.

(C) INCLUSION OF A DEFINITION FOR "VETERINARY DRUGS" IN REGULATION 29

SUBSTANTIAL EQUIVALENCE OPINION

Bovine Lactoferrin (Bioferrin®)

The Food Safety Authority of Ireland (FSAI) received an application in June of 2013 from Glanbia in Ireland for an opinion on the substantial equivalence of its bovine lactoferrin (Bioferrin®) to bovine lactoferrin previously authorised to Morinaga Milk Industry Co. Ltd. through Commission Implementing Decision 2012/725/EU. The source of Glanbia's lactoferrin is cow's milk whey, a by-product of the cheese manufacturing industry and also a source of the authorised lactoferrin. The production process for Bioferrin® is very similar to that for the authorised lactoferrin, yielding products with very similar specifications. Bioferrin® will be designated as "Lactoferrin from cow's milk" in line with Commission Implementing Decision 2012/725/EU, while it will be used only in the food groups set out in Annex II of that Implementing Decision. The applicant considers the ingredient to be novel and fall within the category of "food and food ingredients consisting of, or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use" as set out in *Article 1.2(e)* of the novel food Regulation EC No. 258/97.

Composition

Bioferrin® and the authorised lactoferrin are derived from cow's milk or its derivatives using very similar production and purification processes. A compositional comparison demonstrates the close similarity between Bioferrin® and the authorised bovine lactoferrin in terms of the level of protein, moisture, arsenic, ash etc, as specified in Annex I of the Implementing Decision. The applicant demonstrates batch consistency with respect to the composition of Bioferrin® along with a product stability of greater than 30 months.

Nutritional Value and Metabolism

Bioferrin® and the authorised lactoferrin are derived from cow's milk using very similar processes with the result that the composition of both products is practically

identical. Therefore the nutritional value and metabolism of Bioferrin® is not expected to be any different to the authorised lactoferrin.

Intended Uses

The applicant intends placing the Bioferrin® on the EU market in general foods and foods for particular nutritional (PARNUTS), including foods for special medical purposes (FSMPs) as well as infant and follow-on formulae. The permitted uses and maximum use levels set out in Annex II of Commission Implementing Decision 2012/725/EU that pertains to the authorised bovine lactoferrin will also apply to Bioferrin®.

Level of Undesirable Substances

Bioferrin® and the authorised lactoferrin are produced from the same raw material using a largely similar process and therefore it can be assumed that there will not be any significant differences in the levels of undesirable substances. The applicant demonstrates satisfactory results for lead and arsenic analysis in Bioferrin® along with a microbiological profile similar to that for the authorised lactoferrin.

Conclusions

The FSAI is satisfied from the information provided by the applicant that Glanbia's Bioferrin® is substantially equivalent to bovine lactoferrin authorised to Morinaga Milk Industry Co. Ltd. through Commission Implementing Decision 2012/725/EU. Bioferrin® will be designated as "Lactoferrin from cow's milk" in line with Commission Implementing Decision 2012/725/EU. Bioferrin® will only be used in the food categories and to the maximum use levels set out in Annex II of that Implementing Decision and without prejudice to the provisions of Regulation (EC) No 1925/2006 of the European Parliament and of the Council and Directive 2009/39 of the Parliament and the Council.

SUBSTANTIAL EQUIVALENCE OPINION

Bovine Lactoferrin (Vitalarmor® LACTOFERRIN)

The Food Safety Authority of Ireland (FSAI) received an application in November of 2015 from Armor Protéines S.A.S in France for an opinion on the substantial equivalence of its bovine lactoferrin (Vitalarmor® LACTOFERRIN) to bovine lactoferrin previously authorised to Morinaga Milk Industry Co. Ltd. and Friesland Campania through Commission Implementing Decisions 2012/725/EU and 2012/727/EU, respectively. Commission Implementing Decision (EU) 2015/568 amends the definition of bovine lactoferrin originally set out in Commission Implementing Decision and 2012/725/EU.

Bovine lactoferrin is a naturally occurring iron-binding glycoprotein found in cow's milk. The source of the novel bovine lactoferrin is skimmed cows' milk that has been pasteurised. The novel ingredient is produced in a similar process to that for the EU-authorised comparators, with specifications comparable to those set out in Annex I of the relevant Commission Implementing Decisions. Vitalarmor® LACTOFERRIN will be used in the same foods and at the same maximum use levels as the authorised comparators (Annex II of the Commission Implementing Decisions) and will be designated on those foods as "lactoferrin from cow's milk".

The applicant considers the ingredient to be novel and fall within the category of "food and food ingredients consisting of, or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use" as set out in *Article 1.2(e)* of the novel food Regulation EC No. 258/97.

Composition

Vitalarmor® LACTOFERRIN appears as a light pink powder and is produced from cow's milk to cGMP standards and in accordance with HACCP principles. HPLC analysis of the novel ingredient confirms the identity of the major protein fraction as lactoferrin, with a purity of approximately 97%. The compositional specifications of the novel ingredient are similar to those for the authorised comparators in terms of protein, moisture, ash, arsenic and iron. Lactoferrin content is at >95% of total protein, and the slight differences observed in the mineral content are insignificant as

minerals represent only a minor fraction (≤1%) of the overall ingredient and so have little nutritional impact. A shelf-life of 24 months is proposed for Vitalarmor® LACTOFERRIN when stored dry (humidity <70%) at room temperature (20°C) in the original unopened container, and at 41 months when stored at 4°C.

Nutritional Value and Metabolism

As the composition of the novel and authorised lactoferrin is very similar, the nutritional value and metabolism is not expected to differ significantly.

Intended Uses

Armor Protéines intends placing Vitalarmor® LACTOFERRIN on the EU market as a direct replacement for existing EU-authorised bovine lactoferrin. Food uses and maximum use-levels will not deviate from those specified in Annex II of Commission Implementing Decisions 2012/727/EU and 2012/725/EU which include infant formulae and follow-on formulae, foods for special medical purposes and foods for the general population.

Level of Undesirable Substances

The applicant provides analytical results for contaminants including heavy metals (lead, cadmium, arsenic and mercury), mycotoxins, dioxins and dioxin-like polychlorinated biphenyls (PCBs), and microorganisms, all of which are within relevant EU legislative limits where they exist.

Conclusions

The FSAI is satisfied from the information provided that Vitalarmor® LACTOFERRIN is substantially equivalent to bovine lactoferrin authorised to Morinaga Milk Industry Co. Ltd. and Friesland Campania through Commission Implementing Decisions 2012/725/EU and 2012/727/EU, respectively. Vitalarmor® LACTOFERRIN produced by Armor Protéines S.A.S in France will be used in the food categories and at the maximum use levels set out in Annex II of the relevant Commission Implementing Decisions, without prejudice to the provisions of Regulation (EC) No 1925/2006 and Directive 2009/39. The designation of Vitalarmor® LACTOFERRIN in foodstuffs containing it will be "Lactoferrin from cow's milk".

List of Existing Food Additives (Pages 1 and 6 only)

This list of food additives from natural origin is complied and published by the Ministry of Health and Welfare on April 16, 1996.
These additives are listed here in alphabetic order. The number preceding the name of each additive is the sequence number given to the corresponding additive in the original Japanese list.

Effective from January 30, 2014

236	Absinth extract	A substance composed mainly of sesquiterpenes obtained from the whole absinth grass.
10	α-Acetolactate decarboxylase	-
146	Acid clay	-
147	Acid phosphatase	-
3	Actinidine	-
56	Activated acid clay	-
55	Active carbon	A substance obtained by carbonizing and activating carbon-containing substances.
5	Acylase	-
11	5'-Adenylic acid	-
2	Agarase	-
4	Agrobacterium succinoglycan	A substance composed mainly of succinoglycan obtained from the cultured solution of bacteria belonging to Agrobacteriurn.
17	L-Alanine	-
23	Alginate lyase	-
22	Alginic acid	-
24	Aluminium	-
196	Amino acid-sugar reaction product	A substance obtained by heating the mixture of amino acids and monosaccharides.
14	Aminopeptidase	-
15	alpha-Amylase	-
16	beta-Amylase	-
12	Annatto extract	A substance composed mainly of norbixin and bixin obtained from the seed coats of annatto.
25	Anthocyanase	-
19	Arabino galactan	-
20	L-Arabinose	-
21	L-Arginine	-
145	Artemisia sphaerocephala seed gum	A substance composed mainly of polysaccharides obtained from the seed coats of SABAKU-YOMOGI (*Artemisia sphaerocephala* KRASCH).
6	Ascorbate oxidase	-
7	L-Asparagine	-
8	L-Aspartic acid	-
9	Aspergillus terreus glycoprotein	A substance composed mainly of glycoprotein obtained from the cultured solution of mould belonging to *Aspergillus terreus*.
1	Aureobasidium cultured solution	A substance composed mainly of beta-1, 3-1, 6-glucan obtained from the cultured solution of yeast belonging to *Aureobasidium*.
230	Bacillus natto gum	A substance composed mainly of polyglutamic acid obtained from the cultured solution of bacteria belonging to *Bacillus natto*.
320	Bees wax	A substance composed mainly of myricyl palmitate obtained from honeycomb.
253	Beet red	A substance composed mainly of betanin and isobetanin obtained from beet roots.
303	Bentonite	-
290	Betaine	-
135	Bone carbon black	A substance composed mainly of carbon obtained by carbonizing bones.

List of Existing Food Additives

27	Iso-α-bitter acid	A substance composed mainly of isohumulones obtained from hop flowers.
26	Isoamylase	-
28	Isomaltodextranase	-
29	Itaconic acid	-
161	Jamaica quassia extract	A substance composed mainly of quassin and neoquassin obtained from the trunks/branches or bark of Jamaica quassia trees.
333	Japan wax	A substance composed mainly of glycerol palmitate obtained from the fruits of Japanese wax trees (*Rhus succedanea* LINNE).
51	Japanese persimmon colour	A substance composed mainly of flavonoids obtained from Japanese persimmon fruits.
154	Jelutong	A substance composed mainly of amyrin acetate and polyisoprenes obtained from the secretion of jelutong trees.
307	Jojoba wax	A substance composed mainly of icosenyl icosenate obtained from jojoba fruits.
132	Kaoliang colour	A substance composed mainly of apigeninidin and luteolinidin obtained from kaoliang seeds.
49	Kaolin	-
69	Karaya gum	A substance composed mainly of polysaccharides obtained from the secretion of KARAYA trees (*Sterculia urens* ROXB.) or silk cotton trees (*Cochlospermum gossypium* A.P.DeCandolle).
114	Kooroo colour [Matsudai colour]	A substance obtained by extraction from the roots of SOMEMONO-IMO (Dioscorea matsudai HAYATA).
342	Lac colour	A substance composed mainly of laccaic acids obtained from the secretion of lac scale insects (*Laccifer lacca* KERR).
341	Lactoferrin concentrates	A substance composed mainly of lactoferrin obtained from mammals' milk.
340	Lactoperoxidase	-
343	Lanolin	A substance composed mainly of esters of higher alcohols and α-hydroxylic acids obtained from waxy substances bearing the surface of sheep wool.
358	Leche de vaca	A substance composed mainly of esters of amyrin obtained from the secretion of leche de vaca trees (*Brosimum utile* (H.B.K.) PITT.).
361	L-Leucine	-
359	Levan	A substance composed mainly of polysaccharides obtained from the cultured solution of bacteria belonging to Bacillus subtilis.
75	Licorice extract	A substance composed mainly of glycyrrhizic acid obtained from the roots or rhizomes of Chinese licorice, Xinjiang licorice or licorice.
76	Licorice oli extract	A substance composed mainly of flavonoids obtained from the roots or rhizomes of Chinese licorice, Xinjiang licorice or licorice.
13	Linseed gum	A substance composed mainly of polysaccharides obtained from linseeds.
353	Linter cellulose	A substance composed mainly of cellulose obtained from cotton single pilus.
349	Lipase	-
350	Lipoxygenase	-
352	Liquid paraffin	-
362	Logwood colour	A substance composed mainly of haematoxylin obtained from the heart wood of logwood.
347	L-Lysine	-
348	Lysozyme	-
311	Macrophomopsis gum	A substance composed mainly of polysaccharides obtained from the cultured solution of microorganism belonging to *Macrophomopsis*.
316	Maltose phosphorylase	-
317	Maltotriohydrolase	-

TAIWAN Pages 1 and 59 only)

Standards for Specification, Scope, Application and Limitation of Food Additives

Appendix 1: Standards for Scope, Application and Limitation of Food Additives

01. Preservatives

Code	Food Additive Items	Scope and Application Standards	Limitations
01001	Sorbic Acid	1. Minced fish surimi products, meat products, urchins, caviar, peanut butter, soy sauce preserved vegetables, dried radish containing no less than 25% moisture, pickled vegetables, dried bean curd products, cheeses: not more than 2.0 g/kg calculated as sorbic acid. 2. Cooked beans, soy sauces, miso, dried mullet roe, dried fish and shellfish products, seaweed pastes, soybean curd cheeses, syrup- preserved fruits, dried fruits, cakes and cookies (including steamed Chinese-styled ones), jams, juices, butter, cream, margarine, ketchup, chili sauces, fruit syrups, flavored syrups, other sauces: not more than 1.0 g/kg calculated as sorbic acid. 3. Non-carbonated beverages, carbonated beverages: not more than 0.5 g/kg calculated as sorbic acid. 4. Foods in capsule or tablet form: not more than 2.0 g/kg calculated as sorbic acid.	
01002	Potassium Sorbate	1. Minced fish surimi products, meat products, urchins, caviar, peanut butter, soy sauce preserved vegetables, dried radish containing no less than 25% moisture, pickled vegetables, dried bean curd products, cheeses: not more than 2.0 g/kg calculated as sorbic acid.	

08110	Sodium Glycerophosphate	Special dietary foods: as practically needed.	For supplementing purpose.
08111	Lactulose	Special dietary foods: as practically needed.	For supplementing purpose.
08112	Lactoferrin	1. General foods: not more than 100 mg of lactoferrin for foods labeled with daily dosage. 2. Special dietary foods: as practically needed.	For supplementing purpose.
08113	Calcium Phosphate, Monobasic	1. General foods: not more than 1,800 mg of calcium for foods labeled with daily dosage or for every 300 g of food without daily dosage labeling. 2. Infant (supplementary) foods: not more than 750 mg of calcium for foods labeled with daily dosage or for every 300 g of food without daily dosage labeling.	For supplementing purpose.
08114	Calcium Phosphate, Dibasic	1. General foods: not more than 1,800 mg of calcium for foods labeled with daily dosage or for every 300 g of food without daily dosage labeling. 2. Infant (supplementary) foods: not more than 750 mg of calcium for foods labeled with daily dosage or for every 300 g of food without daily dosage labeling.	For supplementing purpose.
08115	Calcium Phosphate, Dibasic (Anhydrous)	1. General foods: not more than 1,800 mg of calcium for foods labeled with daily dosage or for every 300 g of food without daily dosage labeling. 2. Infant (supplementary) foods: not more than 750 mg of calcium for foods labeled with daily dosage or for every 300 g of food without daily dosage labeling.	For supplementing purpose.
08116	Calcium Phosphate, Tribasic	1. General foods: not more than 1,800 mg of calcium for foods labeled with daily dosage or for every 300 g of food without daily	For supplementing purpose.

PART 7:
APPENDIX 5: Synlait Manufactured Product Examples

The data and information presented within Appendix 5 is Confidential to Synlait Milk Ltd and is **not generally available**.

光明乳业股份有限公司乳业研究院
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电话:(021)66553119
传真:(021)66553708
邮编:200436
Http: // skldb.brightdairy.com

Supporting letter on the use of bovine lactoferrin in infant formula

In a recently completed clinical trial (NCT02239588) evaluating the effects of an infant formula (0-6months) manufactured by Synlait Milk, containing bovine lactoferrin at 60mg/100g, normal growth and development was observed and the formula well tolerated

(Name): 苏米亚

(Signature): (b) (6)

(Date):

光明乳业
BRIGHT DAIRY

803989

- **PURE CANTERBURY** Infant Formula Milk Powder is processed according to the standards of the Codex Alimentarius Commission (CAC) and the "*Chinese Dietary Reference Intakes*" (*Chinese DRIs*),It is made in accordance with the nutritional and dietary needs of babies, and gives babies the required nutritional support.
- **培儿贝瑞**婴儿配方奶粉参考国际食品法典委员会(CAC)的标准以及《中国居民膳食营养素参考摄入量》，针对宝宝膳食结构特点，为宝宝提供多方面的营养支持。

Important Notice/注意事项

冲调前请洗净双手，并保持手部干爽，以免水滴带入导致奶粉受潮、结团，对于0-6月的婴儿最理想的食品是母乳，在母乳不足或无母乳时可食用本产品。调奶时请用专用量匙，按喂哺建议量冲调，未经医生建议，请勿擅自改变冲调比例，否则可能损害宝宝的健康。

Instructions for Use/冲调方法

1.清洗奶瓶、奶嘴、瓶盖；2.沸水中煮五分钟；3.饮用水煮沸后冷却至50°C，将正确水量倒入消毒后的奶瓶；4.使用专用量匙，参照喂哺表加入正确分量奶粉，盖紧瓶盖后摇动使之充分溶解，待冷却至适宜温度后即可喂哺。

产品类别及属性：乳基粉状婴儿配方食品

原产国：新西兰

注册编号：540

企业名称：Synlait Milk Limited

注册地址：1028 Hesterton Road, Rakaia, Canterbury, New Zealand

电话：+64 3 373 3000

中国总经销商：光明乳业股份有限公司

地址：上海市吴中路578号

9 421028 300124

培儿贝瑞
国际母婴中国服务中心
400 700 1717

PPRI00330

PURE CANTERBURY
NEW ZEALAND

PURE CANTERBURY™
培儿贝瑞
新西兰 坎特伯雷平原

原装原罐进口

The Canterbury region is located in the South Island of New Zealand, Pure air, and natural water coming from the snow capped Southern Alps. Cows graze on fresh grass. This young country with its pure ecological environment has created the Pure Canterbury.

雪山牧场，鲜嫩的牧草，清新的空气——是新西兰为之骄傲的自然环境，这片年轻，充满生机的土地缔造了**培儿贝瑞**的纯净品质。

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O·P·O

培儿贝瑞亲衡 系统

净含量:900克 新西兰 原装原罐进口

1

适宜人群：0-6个月婴儿

NEW ZEALAND MADE

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Ingredients/配料

Ingredients: Skim milk, Whole milk, Lactose, Refined vegetable oils (Soya bean oil, Coconut oil, Sunflowerseed oil, Rapeseed oil), Demineralized whey powder, Whey protein concentrate, 1,3-Dioleoyl 2-palmitoyl Triglyceride, Polyfructose, Galacto-oligosaccharide, ARA(Arachidonic acid oil), DHA(Docosahexaenoic acid oil), Minerals (Potassium chloride, Sodium citrate, Magnesium chloride, Calcium carbonate, Ferrous gluconate, Zinc sulfate, Copper gluconate, Manganese sulfate, Potassium iodide, Sodium selenite), Vitamins(L-Ascorbic acid, Choline chloride, dl-α-Tocopherol acetate, Calcium D-Pantothenate,Vitamin A Acetate, Nicotinamide, Vitamin D3, Cyanocobalamin, Phytonadione, Thiamine hydrochloride, Riboflavin, Pyridoxine hydrochloride, Folic acid, D-Biotin), Taurine, Nucleotides (Guanosine 5' Monophosphate Disodium, Inosine 5' Monophosphate Disodium, Uridine 5' Monophosphate Disodium, Adenosine 5' Monophosphate, Cytidine 5' Monophosphate), Lactoferrin, Citric acid, Calcium hydroxide, Ascorbyl palmitate.

配料：脱脂牛奶、全脂牛奶、乳糖、精炼植物油(大豆油、椰子油、葵花籽油、菜籽油)、脱盐乳清粉、浓缩乳清蛋白粉、1，3-二油酸 2-棕榈酸甘油三酯、多聚果糖、低聚半乳糖、ARA(花生四烯酸油脂)、DHA(二十二碳六烯酸油脂)、矿物质(氯化钾、柠檬酸钠、氯化镁、碳酸钙、葡萄糖酸亚铁、硫酸锌、葡萄糖酸铜、硫酸锰、碘化钾、亚硒酸钠)、维生素(L-抗坏血酸、氯化胆碱、dl-α-醋酸生育酚、D-泛酸钙、醋酸维生素A、烟酰胺、维生素D3、氰钴胺、植物甲萘醌、盐酸硫胺素、核黄素、盐酸吡哆醇、叶酸、D-生物素)、牛磺酸、核苷酸(5'-乌苷酸二钠、5'-肌苷酸二钠、5'-尿苷酸二钠、5'单磷酸腺苷、5'单磷酸胞苷)、乳铁蛋白、柠檬酸、氢氧化钙、抗坏血酸棕榈酸酯。

Suggested Feeding Table/喂哺用量建议表

1平匙奶粉约等于7.5克冲50mL水

婴儿年龄	温开水量(毫升)	量匙数/次	喂哺次数/天
0-2 weeks(周)	50	1	7-9
2-4 weeks(周)	100	2	6-8
1-2 months(月)	150	3	4-6
2-3 months(月)	150	3	5-6
3-6 months(月)	200	4	4-5

*喂哺用量建议表是根据平均的需要量制定的。

Storage Conditions/贮存条件

产品应存放于阴凉干燥处，常温保存(室温20-25°C)，以免遇高温后影响产品品质。开罐后请务必盖紧塑料盖，并请于四周内食用完毕。

生产日期MFD(YYYY/MM/DD)、保质期至USE BY (YYYY/MM/DD)及产品批号(LOT)请见罐底所示。请在保质期前食用。

Nutrition Information/营养成分表

Nutrients 营养成分	Unit 单位	Average content/100g 每100克(或每单位含量)	Average content/100mL 每100毫升(或每罐每单位含量)
能量 (Energy)	kJ	2095	273kJ/100mL
蛋白质 (Protein)	g	11.5	0.55
乳铁蛋白 (Lactoferrin)	mg	30	1.4
脂肪 (Fat)	g	25.9	1.24
1,3-二油酸 2-棕榈酸三油酸甘油酯 1,3-Dioleoyl 2-palmitoyl Triglyceride	g	3.3	0.16
亚油酸 (Linoleic acid)	g	4.16	0.20
α-亚麻酸 (α-Linolenic acid)	mg	310	15
二十二碳六烯酸 (DHA)	mg	50	2.4
二十碳四烯酸 (ARA)	mg	80	3.8
碳水化合物 (Carbohydrate)	g	54.2	2.6
多聚果糖 (Polyfructose)	mg	2000	93.4
低聚半乳糖 (GOS)	mg	400	19.1
牛磺酸 (Taurine)	mg	44	2
核苷酸 (Nucleotides)	mg	23.5	1.1
维生素A (Vitamin A)	μg RE	500	24
维生素D (Vitamin D)	μg	9.0	0.43
维生素E (Vitamin E)	mg α-TE	11.4	0.54
维生素K (Vitamin K)	μg	40.5	1.9
维生素B1 (Vitamin B1)	μg	786	38
维生素B2 (Vitamin B2)	μg	1420	68
维生素B6 (Vitamin B6)	μg	424	20.7
维生素B12 (Vitamin B12)	μg	1.80	0.09
烟酸 (Niacin)	μg	4800	229
叶酸 (Folic acid)	μg	145	6.9
泛酸 (Pantothenic acid)	μg	5800	277
维生素C (Vitamin C)	mg	180	8.6
生物素 (Biotin)	μg	21	1.0
胆碱 (Choline)	mg	115	5.5
钠 (Sodium)	mg	130	6
钾 (Potassium)	mg	545	25
铜 (Copper)	μg	328	15.6
镁 (Magnesium)	mg	46	2.2
铁 (Iron)	mg	5.0	0.24
锌 (Zinc)	mg	5.2	0.25
锰 (Manganese)	μg	101	4.8
钙 (Calcium)	mg	359	17
磷 (Phosphorus)	mg	220	10
碘 (Iodine)	μg	93	4.4
氯 (Chloride)	mg	359	17
硒 (Selenium)	μg	15	0.72

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803794 MAGENTA CYAN BLACK A2 BROWN BLUE

Part 7, Appendix 5
A5: 4

INGREDIENTS/配料: 乳粉体(乳糖、脱盐乳清粉、乳清蛋白粉)、植物油、全脂牛奶、低脂半乳糖、脱脂牛奶、矿物质(柠檬酸钠、磷酸氢钙、氯化钾、碳酸钙、氯化铁、磷酸氢二钾、硫酸亚铁、硫酸锌、亚硒酸钠、硫酸铜、硫酸锰、硫酸镁、硫化钙)、花生四烯酸油脂、金枪鱼油、维生素(L-抗坏血酸、氯化胆碱、dl-α-醋酸生育酚、肌醇、醋酸维生素A、烟酰胺、D-泛酸钙、维生素D3、植物甾醇酯、盐酸硫胺素、盐酸吡哆醇、叶酸、核黄素、叶酸、D-生物素)、氯氧化钾、牛磺酸、乳铁蛋白、核苷酸(5'-单磷酸腺苷、5'-尿苷酸二钠、5'-单磷酸胞苷、5'-肌苷酸二钠、5'-乌苷酸二钠)、柠檬酸。
左旋肉碱。

ALLERGY CAUTION/过敏提示: 本产品含有大豆、鱼油、牛奶成分。

STORAGE CONDITIONS/贮存条件: 如果罐装铝箔封口被破坏或缺失请勿使用。请将奇迹版的奶粉存放第。请产在阴凉干燥的地方。每次开罐使用后务必盖紧奇迹塑料盖。开罐后应在4个星期内用完。听装规格均按重量计算(而非按容量计算)。

IMPORTANT NOTICE/重要信息: 对于0-6月的婴儿最理想的食品是母乳,在母乳不足或无母乳时可食用本产品。

WARNING/警告: 严格按说明操作,调配要求准备奶瓶和奶嘴,除非医生另有建议,否则请勿改变奶粉的冲调比例。不正确的冲调方法可能会严重危及宝宝健康。

PRODUCT TYPE/产品类别及属性: 乳基婴儿配方奶粉。

MANUFACTURE DATE/生产日期: (年/月/日), 保质期至(年/月/日), 生产批号见罐底。

原产国: 新西兰
出品商: A2 Infant Nutrition Ltd
生产商: Synlait Milk Limited
地址: 1028 Heslerton Road, Rakaia, Canterbury, New Zealand
生产商注册编号: 540

进口商: 中国农垦控股上海公司
地址: 上海市浦东新区浦东大道2123号3层E区1820-1821室
邮编: 200135
客服热线: 4008204056
www.a2nutrition.cn
PPRI00160

POSITION ONLY 100%
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营养成分表 NUTRITION INFORMATION 营养素/Nutrients	单位 Unit	平均含量/Average Quantity 每100克奶粉 Per 100g	每100千焦 Per 100kJ
能量/energy	kJ	2103	100
蛋白质/protein	g	10.7	0.51
- 乳清蛋白/whey protein	g	6.42	0.31
- 酪蛋白/casein protein	g	4.28	0.20
脂肪/fat	g	26.0	1.24
- 亚油酸/linoleic acid	g	4.20	0.20
- α-亚麻酸/α-linolenic acid (ALA)	mg	450	21.4
亚油酸与α-亚麻酸(ALA)比值		9.3:1	9.3:1
- 二十二碳六烯酸/ docosahexaenoic acid (DHA)	mg	90.0	4.28
二十二碳六烯酸/ docosahexaenoic acid (DHA)	%总脂肪酸	0.37	0.37
- 二十碳四烯酸/arachidonic acid (ARA)	mg	140	6.66
二十碳四烯酸/arachidonic acid (ARA)	%总脂肪酸	0.57	0.57
碳水化合物/carbohydrate	g	54.9	2.61
- 乳糖/lactose	g	52.0	2.47
低聚半乳糖/ galacto-oligosaccharides (GOS)	g	3.00	0.14
维生素 A/vitamin A	μg RE	510	24.3
维生素 D/vitamin D	μg	6.90	0.33
维生素 E/vitamin E	mg α-TE	7.50	0.36
维生素 K1/vitamin K1	μg	46.0	2.19
维生素 B1/vitamin B1	μg	550	26.2
维生素 B2/vitamin B2	μg	1010	48.0
维生素 B6/vitamin B6	μg	415	19.7
维生素 B12/vitamin B12	μg	2.00	0.10
烟酸/niacin	μg	3700	176
叶酸/folic acid	μg	75.0	3.57
泛酸/pantothenic acid	μg	3500	166
维生素 C/vitamin C	mg	145	6.90
生物素/biotin	μg	22.5	1.07
胆碱/choline	mg	94.0	4.47
肌醇/inositol	mg	32.7	1.56
钠/sodium	mg	165	7.85
钾/potassium	mg	540	25.7
铜/copper	μg	365	17.4
镁/magnesium	mg	48.0	2.28
铁/iron	mg	5.50	0.26
锌/zinc	mg	5.10	0.24
锰/manganese	μg	320	15.2
钙/calcium	mg	390	18.5
磷/phosphorus	mg	260	12.4
钙磷比值/Ca:P		1.5:1	1.5:1
碘/iodine	μg	70.0	3.33
氯/chlorine	mg	340	16.2
硒/selenium	μg	18.3	0.87
牛磺酸/taurine	mg	39.0	1.85
左旋肉碱/l-carnitine	mg	8.50	0.40
核苷酸/nucleotides	mg	25.0	1.19
乳铁蛋白/lactoferrin	mg	30.0	1.43

The a2 Milk Company™

PROUDLY MADE IN NEW ZEALAND 新西兰原产原装进口

a2 PLATINUM® 白金

婴儿配方奶粉

升级配方[1]

a2™ 源乳™配方
专利应用的A2奶牛基因检测[2]

✓ TRUE a2™品质保证
✓ 含有DHA
✓ 含有膳食纤维(低聚半乳糖)

1
2 3

婴儿配方奶粉
0-6个月婴儿

净含量: 900克

- ✓ a2™ Natural Sourced Milk
  a2™源乳™配方
- ✓ Patented use of bovine genotype testing for A2 beta-casein
  专利应用的A2 β-酪蛋白奶牛基因检测[2]
- ✓ TRUE a2™ quality assurance
  TRUE a2™品质保证

Preparation Instructions 冲调方法

1. 冲调奶粉前要洗手。煮沸或使用天普器对所有喂食用具进行消毒。
2. 煮沸饮用水，晾至适温，勺量将水注入经消毒的奶瓶中，晾至温热喂食宝宝。
3. 仅使用罐中配备的量勺。轻轻倒满量勺，并用罐口的刮平器刮平。不要挤压奶粉。
4. 将50毫升水加一平勺奶粉。盖上瓶盖轻快地摇晃以加速其溶解。
5. 在手腕上测试温度是否合适。冲调好奶粉后要立即喂食。没有吃完的要倒掉。

奶粉检查冲调。
冲调完毕后应尽快喂食。

a2 PLATINUM® Premium Infant & Growing Up Milk formulas are made and packed in New Zealand, using strict quality and safety practices, it's the only one that combines age-appropriate key ingredients with patented properties of A2 beta-casein. This means that a2 PLATINUM® Premium Infant & Growing Up Milk formulas provide your baby with advanced tailored nutrition you can trust.

a2 PLATINUM® 白金™ 系列婴幼儿配方奶粉新西兰原产原装全进口，执行严格的品质与安全标准。独特的产品配方糅选了专利A2 β-酪蛋白[3]，同时针对婴幼儿不同生长阶段的营养需求添加了各种营养成分。a2 PLATINUM® 白金™ 系列婴幼儿配方奶粉给予宝宝全面营养，值得信赖。

1 a2 PLATINUM® 白金™ 婴儿配方奶粉

Specially formulated for babies from birth to 6 months old. It is nutritionally complete, providing key ingredients essential for growth and development. The exclusive formulation is based on patented properties of A2 beta-casein and patented use of bovine genotype testing for A2 beta-casein.
本品适用于0-6个月的宝宝。本产品营养全面，提供了婴儿生长发育所需的各种营养成分。独特的产品基于专利A2 β-酪蛋白[3]及专利应用的奶牛基因检测技术[2]。

FEEDING GUIDE / 喂哺指导

Age of Baby 婴儿年龄	Cooked Boiled Water (mL) 温开水量(毫升)	Level Scoops* 奶粉(勺)	Formula Feeds Per Day 每日喂哺次数
0-2 weeks (周)	50	1	7-9
2-8 weeks (周)	100	2	5-6
2-4 months (月)	150	3	5-6
4-6 months (月)	200	4	4-5

*1 量勺奶粉≈7.5g
请注意: 每50毫升水加一平勺奶粉, 冲调的50毫升的配方奶, 本喂哺指导只是一般的指引, 在最初的几个星期, 基生儿可能无法完成一个完整喂哺量, 没有吃完的奶要倒掉。

a2 Milk®, a2 Platinum®, The a2 Milk Company™是a2牛奶公司的注册商标。

参考资料:
1. 和原配方相比
2. 专利号: ZL 0381 7 445.3
3. 专利号: ZL 2003 8 0104926.5

803794

CLEAR BASE COAT & VARNISH LIMIT
L: 391.00mm x H: 162.00mm

BASE COLOUR LIMIT (MAXIMUM PRINT AREA)
L: 393.00mm x H: 160.00mm

MAXIMUM TEXT LIMIT
L: 393.00mm x H: 149.00mm

BARCODE LIMIT
L: 70.00mm x H: 50.00mm

803760 GOLD MAGENTA CYAN PURPLE DK BLUE BLACK

PACKAGING DYNAMICS (AUST) PTY LTD

Jamestrong

JAMESTRONG CONTACT: Daniel Prentier
ARTWORK CREATION DATE: 20/08/14
CLIENT: Synlait
DESCRIPTION: Akara Step 1 900g
JOB CODE: PD803760
PDA JOB NUMBER: JN17180
TEMPLATE: 127 x 162.5 NZ
DATE LAST AMENDED: 31/04/15
BY: ARTWORKER: Darren
SUPERCEDES CODE: 8058/3
DECORATION PLANT: KMP

COLOUR:

BASE:
PRIME
WHITE SHARP
GOLD
WHITE OPEN
MAGENTA
YELLOW
CYAN
PURPLE
BLUE
BLACK

ALTERATIONS:
03/09/14: Changed artwork from Coat to Print White adding 2 x Whites, Changed PMS 3135 to process.
09/09/14: Rework artwork image colours to match that of supplied cans.
Previous Print.
31.04.15 - placed in new artwork.

PLATES AFFECTED:
31.04.15 - All Plates

TECHNICAL APPROVAL
NAME:
DATE:
PROOF: OK ○
SEPARATIONS: OK ○
COMMENTS:

GENERAL CHECKS
○ 2mm CLEARANCE FROM VARNISH EDGE (BODY ART) CHECKED
○ MAX ART LIMIT CHECKED & APPROVED
○ BARCODE COLOR & ORIENTATION APPROVED BY MANUFACTURING
○ ALL FONT SIZES CHECKED & APPROVED BY DECORATION
○ IF REQUIRED - GOLD INK OR VARNISH SPECIFIED

BASE COLOUR LIMIT [ALD]
L: 393.00mm (A) x H: 160.00mm (D)
NO OVERCAP
L: 393.00 (A) x H: 154.00mm (D)
Finished Color must not bleed past the 'base colour limit'.
Graphic elements must be contained within the 'maximum artwork limit'.

DISCLAIMER:
Please note that this proof is made by superimposing dyed photographic images of each colour over one another to produce the finished proof.

Whilst we endeavour to ensure that this proof is accurate in terms of content, we cannot guarantee that the printed image will match the proof for colour & shading although every attempt will be made to achieve target as close as possible.

Please check this proof thoroughly before signing.

If CUSTOMER requires a Colour match additional to the Digital Proof, Jamestrong Packaging can arrange on request - Ink Colour Roll-outs for Special and/or PMS colours.

CUSTOMER APPROVAL SECTION
NAME & DATE:
SIGNATURE: PROOF: OK ○
INK roll-outs Special and/or PMS Colours: OK ○
INK ORDERING AND PRINT PRODUCTION CANNOT BE PLANNED UNTIL SIGNED DIGITAL PROOF (and if requested signed ink roll-outs) ARE RECEIVED AT JAMESTRONG PACKAGING.
COMMENTS:
YOUR APPROVAL OF THIS PROOF WILL ACTION THE DESTRUCTION OF THE SUPERSEDED DESIGN PRINTING PLATES. OK ○

PART 7:
APPENDIX 6: Curriculum vitae of GRAS Panel Members

The data and information presented within Appendix 6 is Confidential to each of the GRAS Panel Members and is **not generally available**.

Pages 000272-000397 of Curriculum Vitae removed in accordance with the Privacy Act of 1974.

SUBMISSION END