Proliant
DAIRY INGREDIENTS

May 8, 2020

Dr. Paulette Gaynor
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Campus Drive
College Park, MD 20740

Dear Dr. Gaynor,

Re: GRAS Notice for Whey Permeate

In accordance with 21 CFR §170 Subpart E consisting of §170.203 through 170.285, Proliant Dairy, LLC. hereby informs the United States Food and Drug Administration of the conclusion that the intended use of Whey Permeate as nutritive carbohydrate sweetener in chocolates, where allowed as optional ingredient, is Generally Recognized as Safe (GRAS), based on scientific procedures. Information setting forth the basis for this GRAS conclusion is presented in the enclosed notice. The intended use of Whey Permeate as nutritive carbohydrate sweetener in chocolates is therefore not subject to the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act. Included in this submission is one paper copy of the GRAS Notice, as well as a compact disc (CD) that contains an electronic copy of all enclosed files. The electronic and paper copies of the GRAS Notice are identical. Should you have any questions or concerns regarding this GRAS Notice, please do not hesitate to contact me, so that we may provide a response in a timely manner. I look forward to receiving acknowledgment of receipt of this notice.

Yours sincerely,

Sylvia A. Bergman, Ph.D.
Director, Regulatory Technical Support
Proliant Dairy, LLC.

GRAS Notice for Whey Permeate

Prepared for:
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Campus Drive
College Park, MD 20740
USA

Submitted by:
Proliant Dairy, LLC.
2425 SE Oak Tree Ct
Ankeny, IA 50021

May 8, 2020

GRAS NOTICE FOR WHEY PERMEATE

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Part 1 – Signed statements and certification

1.1 Applicability of 21 C.F.R. part 170, subpart E

We submit this generally recognized as safe (GRAS) notice in accordance with 21 C.F.R. Part 170, subpart E, consisting of sections 170.203 through 170.285.

1.2 Name and address of the notifier

Proliant Dairy, LLC.
2425 SE Oak Tree Ct
Ankeny, IA 50021 USA

All communications on this matter may be sent to:

Sylvia A. Bergman, Ph.D.
Director, Regulatory Technical Support
Proliant Dairy, LLC.

1.3 Common Name of the notified substance

Whey Permeate
Trade name: VersiLac® Dairy Product Solids
Also known by the synonyms: Dairy Product Solids, Modified Whey, Whey Solids, Deproteinized Whey, Dairy Permeate, Milk Permeate.

1.4 Applicable conditions of use of the notified substance

The whey permeate produced from whey is intended for use as a nutritive carbohydrate sweetener in chocolates (i.e. white, sweet, milk and dark chocolate), which either allow under their respective Standard of Identity (SOI) an optional ingredient of a nutritive carbohydrate sweetener or do not have a SOI (i.e. dark chocolate), at a typical level of 2-8% and a maximum level of 20%. It is not intended to contribute to any milk component requirements needed to satisfy a particular SOI.

1.5 Basis for the GRAS determination

Proliant Dairy, LLC. hereby notifies the Agency of its determination that their whey permeate (VersiLac® Dairy Product Solids) is Generally Recognized as Safe (GRAS), consistent with Section 201(s) of the Federal Food, Drug, and Cosmetic Act. This GRAS conclusion is based on scientific procedures in accordance with 21 C.F.R. §170.30(a) and (b) and conforms to the guidance issued by the Food and Drug Administration (FDA) under 21 C.F.R. §170.36, 81 Fed. Reg. 54960 (Aug. 17, 2016).

1.6 Exclusion from premarket approval

Proliant Dairy, LLC. has concluded that its whey permeate is GRAS and not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act. The whey permeate meets the required specifications when used as a nutritive carbohydrate sweetener in

chocolates (i.e. white, sweet, milk and dark chocolate), which either allow under their current SOI an optional ingredient of a nutritive carbohydrate sweetener or do not have a SOI (i.e. dark chocolate). It is not intended to contribute to any milk component requirements needed to satisfy a particular SOI.

1.7 Availability of data and information

The information for this GRAS conclusion including analytical data, published studies, and information that are the basis for this GRAS determination are available to FDA upon request as required by 21 C.F.R. § 170.225(c)(7)(ii)(A) or (B) by contacting:

Sylvia A. Bergman, Ph.D.
Director, Regulatory Technical Support
Proliant Dairy, LLC.
2425 SE Oak Tree Ct
Ankeny, IA 50021

1.8 Applicability of FOIA exemptions

Proliant Dairy, LLC. is not claiming any information in Parts 2 through 7 of this document as trade secret, confidential or financial information that is privileged or confidential. Thus, all information and data in this submission are not exempt from the Freedom of Information Act (FOIA), 5 U.S.C. Section 552.

1.9 Certification

Proliant Dairy, LLC. certifies that this GRAS conclusion is based on representative data from Proliant Dairy, LLC. required for the safety and GRAS status of the use of whey permeate. To the best our knowledge, this GRAS Notice (GRN) is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to us and pertinent to the evaluation of safety and GRAS status of the use of the substance.

Signed:

[redacted]

May 8, 2020

Sylvia A. Bergman, Ph.D.
Director, Regulatory Technical Support
Proliant Dairy, LLC.

Date: May 8, 2020

Part 2 – Identity, method of manufacture, specifications, and physical or technical effect

2.1 Identity of the notified substance

Whey permeate (VersiLac® Dairy Product Solids) is produced by the removal of protein and fat from whey to the extent practical, resulting in a product with a high concentration of lactose.

2.1.1 Common or usual name

Common name: Whey permeate

Examples of synonyms: Dairy Product Solids, Modified Whey, Whey Solids, Deproteinized Whey, Dairy Permeate, Milk Permeate.

2.1.2 Trade Name: VersiLac® Dairy Product Solids

2.2 Description of the method of manufacture

Figure 1 provides a step-by-step flow chart of the manufacturing process for VersiLac® Dairy Product Solids, the spray-dried, deproteinized dairy/whey product solids.

Liquid deproteinized whey (DPW)/Dairy Product Solids (DPS) are sourced from approved dairy facilities with adherence to Good Manufacturing Practices (cGMP) for food (21 CFR Part 110).

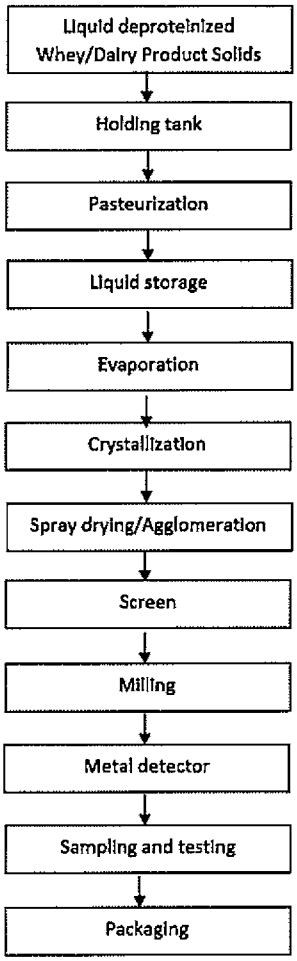
The raw material received must be at >145°F (74.4°C), have a typical solids content of >42% and a pH between 5.0 to 5.8 (neat). To ensure pathogen control and compliance with regulatory limits in the finished product, liquid DPW/DPS are pasteurized in accordance with the provisions of the Pasteurized Milk Ordinance (PMO) at a minimum temperature of 166°F (74.4°C) for a minimum of 15 seconds prior to being pumped to the liquid storage silo until further processing. From there it will be further concentrated by evaporation from approximately 42 to 75% solids at 195°F to 205°F.

It then gets transferred to crystallization tanks, where crystallization process takes place slowly, according to predetermined time/temperature program. After crystallization, the permeate is spray dried and agglomerated. Following sifting, material that does not pass through the screen will be ground in a hammer mill to produce ground deproteinized whey. Dried powder is transferred to a holding silo in preparation for packaging.

A food grade oil-based defoamer such as MAGRABAR® PD-602 may be added as needed as a processing aid to prevent cavitation of pumps throughout the process. The processing aids meet the standard as outlined in the 'Guidelines on Substances used as Processing Aids' (CXG 75-2010).

Figure 1: VersiLac Process Flow Chart (spray-dried, deproteinized Dairy/Whey Product Solids)

Figure 1: VersiLac Process flow chart (spray-dried, deproteinized Dairy/Whey Product Solids)



2.3 Specifications and Identity

The typical composition of the whey permeate is provided in Table 1.

Table 1: Typical Composition of Whey Permeate

Parameter	Specifications	Test Method
Protein (as is), %	2.0-4.5	NIR based on AOAC 991.20.1
Fat, %	0.0- 0.2	NIR based on AOAC 989.05

Carbohydrate (Lactose), %	80.0 - 90.0	NIR based on 'by difference'
Ash, %	6.0 - 9.0	NIR based on AOAC 930.30
Moisture, %	1.0 - 5.0	NIR based on SMEDP 15.113

The microbiological and lead specifications are provided in Table 2.

Table 2: Microbiological and Lead Specifications of Whey Permeate

Parameter	Specifications	Test Method
Standard plate count (SPC), CFU/g	<30,000	AOAC 966.23
Coliforms, MPN/g	<10	AOAC 966.24
E.coli, MPN/g	<3.0	AOAC 966.24
Salmonella	Neg/750g	AOAC 2004.03
Listeria -ELFA	Neg/25g	AOAC 2004.06
Staphylococcus aureus, CFU/g	<100	AOAC 975.55
Yeast, CFU/g	<100	FDA-BAM 7th Ed.
Mold, CFU/g	<100	FDA-BAM 7th Ed.
Lead, ppm	<0.1	EPA 3050/6020 USP730

Three non-consecutive batch analyses are provided in Table 3.

Table 3: Three Non-consecutive Batch Analysis of Whey Permeate

Parameter	Test Method	Specifications	M902311	M917011	M925011
CRUDE PROTEIN %	NIR based on AOAC 991.20.1	2.0-4.5	3.9	3.7	3.5

CRUDE FAT %	NIR based on AOAC 989.05	0.0- 0.2	0.1	0.1	0.1
CARBOHYDRATES % (LACTOSE)	NIR based on 'by difference'	80.0 - 90.0	86.7	86.9	86.9
ASH %	NIR based on AOAC 930.30	6.0 - 9.0	7.5	7.5	7.7
MOISTURE %	NIR based on SMEDP 15.113	1.0 - 5.0	1.7	1.5	1.5
STANDARD PLATE COUNT (CFU/g)	AOAC 966.23	<30,000	<100	<100	<100
Coliforms, MPN/g	AOAC 966.24	<10	<3	<3	<3
E.coli, MPN/g	AOAC 966.24	<3.0	<3	<3	<3
Salmonella	AOAC 2004.03	Neg/750g	Neg/750g	Neg/750g	Neg/750g
Listeria -ELFA	AOAC 2004.06	Neg/25g	Neg/25g	Neg/25g	Neg/25g
Staphylococcus aureus	AOAC 975.55	<100	<10	<10	<10
Yeast, CFU/g	FDA-BAM 7th Ed.	<100	<10	<10	<10
Mold, CFU/g	FDA-BAM 7th Ed.	<100	<10	<10	10
LEAD* (ppm)	EPA 3050/6020 USP730	<0.1		<0.01	

*Annual Testing

2.4 Contaminants

The whey permeate is produced in accordance with good manufacturing practices and meets applicable state and federal regulations. The whey permeate is also tested annually for pesticidal residue, Heavy metals, Aflatoxin Ml, Nitrate, Nitrite, Bacillus cereus, Cronobacter spp, and Sulfite Reducing Clostridia.

Part 3 – Dietary exposure

3.1 Estimate of Dietary Exposure

The whey permeate produced from whey is intended for use as a nutritive carbohydrate sweetener (NCS) in chocolates (i.e. white, sweet, milk and dark chocolate), at a typical level of 2-8% and a maximum level of 20%.

Based on the 1994-96 Continuing Survey of Food Intakes by Individuals (CSFII 1994-96), conducted by the U.S. Department of Agriculture (USDA), the mean quantities of "candy containing chocolate" consumed per eating occasion (eater-only) (Table 1.109), in a day (eater-only) (Table 2.094), and per person per day (per capita) (Appendix Table B) are 44 g, 48 g, and 4 g, respectively, for all individuals age 2 and over.[1] The category of "candy containing chocolate" includes plain milk chocolate, chocolate candy bars, and all chocolate-flavored or chocolate-covered candy reported separately.

Based on FDA's Guidance for Industry Reference Amounts Customarily Consumed (RACC): List of Products for Each Product Category, the reference amount, or standard serving size, for "all other candies" is 30 g per eating occasion.[2] The category of "all other candies" includes fruits or nuts coated with candy (e.g., chocolate-coated raisins or nuts, yogurt-coated raisins or nuts), fruit-based sweets (e.g., gummy bears) and marshmallow candies (e.g., chocolate-coated marshmallows, coconut-coated marshmallows, marshmallow chickens, marshmallow cream), and chocolate bars (solid or chocolate covered candy). The RACC supports the view that the CSFII consumption data are not likely to understate actual chocolate intake and therefore are still an appropriate measurement of daily intake.

To estimate the dietary exposure, we conservatively use the highest consumption value of 48 g/day for "candy containing chocolate" and the upper typical use level of the whey permeate of 8% and the maximum use level of 20% for the exposure calculation as follows.

If whey permeate is used in chocolate at 8%, the exposure to the whey permeate would be:

48 g/day x 8% = 3.84 g/day

If whey permeate is used in chocolate at 20%, the exposure to the whey permeate would be:

48 g/day x 20% = 9.6 g/day

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[1] Smiciklas-Wright, H., D.C. Mitchell, S.J. Mickle, A.J. Cook, and J.D. Goldman. 2002. Foods Commonly Eaten in the United States: Quantities Consumed Per Eating Occasion and in a Day, 1994-1996. U.S. Department of Agriculture NFS Report No. 96-5, pre-publication version, 252 pp. Available online: www.barc.usda.gov/bhnrc/foodsurvey/Products9496.html.

[2] FDA Reference Amounts Customarily Consumed: List of Products for Each Product Category: Guidance for Industry. February 2018. Available online: https://www.fda.gov/media/102587/download

Part 4 – Self-limiting levels of use

The whey permeate has self-limiting levels of use due to the definition of the chocolate.

Part 5 – Experience based on common use in food before 1958

The statutory basis for the conclusion of GRAS status of the whey permeate in this document is not based on common use in foods before 1958. The GRAS determination is based on scientific procedures. However, as described below, the whey permeate source material, milk or whey, has been commonly used in foods prior to 1958.

Part 6 – Narrative

6.1 Introduction

The conclusion that the whey permeate is GRAS under the conditions of its intended use in chocolate is based on (1) regulatory clearances and existing GRAS notices on whey and whey related products, (2) human consumption of milk, whey, and whey products, (3) the composition and manufacturing process of the whey permeate, and (4) the intended uses that result in safe dietary exposure.

6.2 Regulatory clearances and existing GRAS notices

FDA has a regulatory clearance on dairy product solids for use in foods in general (GRAS Notice 37). Also, its source material and related substances such as whey and whey protein are GRAS affirmed, whereas its primary component lactose is also approved as a nutritive carbohydrate sweetener under 21 C.F.R.§ 168.122 and permitted for use in food. In addition, FDA has issued "no questions" letters to GRAS Notices on various whey and whey-related products. The FDA's clearances on these substances demonstrate the safety of whey permeate. Table 4 summarizes whey and whey-related substances affirmed by FDA as GRAS for direct use in food.

The International Dairy Federation (IDF) collaborated with Codex Alimentarius in the development of a science-based international standard to clarify the identity, composition, safety, and quality of dairy permeate powders for use in food (CXS 331-2017).

Lactose content is included in the table. The level of lactose is 80.0-90.0% in the whey permeate, higher than that in whey (61-75%), reduced lactose whey (≤ 60%), and whey protein concentrate (maximum 60%), and similar to that in reduced minerals whey (maximum 85%).

Table 4: Whey and Whey Related Substances Affirmed by FDA as GRAS for Direct Use in Food

Regulation (21 C.F.R.)	Substance	Lactose Content	Uses
§ 184.1979	Whey	61-75%	Used in food in accordance with good manufacturing practice
§ 184.1979a	Reduced lactose whey	≤ 60%	Used in food in accordance with good manufacturing practice
§ 184.1979b	Reduced minerals whey	maximum 85%	Used in food in accordance with good manufacturing practice

Regulation (21 C.F.R.)	Substance	Lactose Content	Uses
§ 184.1979c	Whey protein concentrate	maximum 60%	Used in food in accordance with good manufacturing practice

In addition, the following GRAS Notices were submitted to FDA on whey and whey-related substances (Table 5).

Table 5: GRAS Notices Submitted to FDA on Whey and Whey-Related Substances for Direct Use in Food

GRN No.	Substance	Lactose Content	Uses	Status
809	Fractionated whey protein concentrate (WPC) containing 41% alpha-lactalbumin	≤ 10%	For use as a source of protein in infant formula at a use level of 2.5 g/L or up to 8.3 g/L. The EDI of WPC at the 90th percentile is 1.72 g/kg bw/day.	FDA issued a "no questions" letter in May 2019.
644	Non-fat dry goat milk and goat whey protein	45.3% in NFDGM	For use as a source of protein in infant formula for full-term gestation infants to 12 months of age. Non-fat dry goat milk will be added at 57% (±5%) of the protein blend. The remaining 43% (±5%) of total protein will be provided by goat whey protein. The mean and 90th percentile dietary exposures to GWPC by infants aged 0 to 6 months (users-only) are estimated at 11.8 and 17.0 g/d (1.94 and 3.12 mg/kg bw/d), respectively. The mean and 90th percentile dietary exposures to GWPC by infants aged 7 to 12 months (users-only) are estimated at 9.7 and 15.4 g/d (1.09 and 1.81 mg/kg bw/d), respectively.	FDA issued a "no questions" letter in Oct. 2016
633	Concentrated milk protein with a ≥ 60:40 whey: case in ratio	Not specified	For use as an emulsifier, flavoring agent, formulation aid, humectants, stabilizer, thickener, texturizers, and protein source in the following food categories at varying use levels depending on technical effect: meal replacements and meal supplements; powdered nutritional beverages; nutritional	FDA issued a "no questions" letter in Sep. 2016

			bars; acidified sports beverages; milk products; yogurt and fermented milk products; non-standardized cheese products; spreads, dips and cream substitutes; frozen dairy desserts and mixes; desserts and mousses; confections; snack foods; coatings and fillings; salad dressings; soups, soup mixes, and sauces. The mean daily intake per capita is 0.044 g/p/day and "eaters only" is 0.44 g/p/day.	
612	Fractionated whey protein isolate containing cows milk derived lactoferrin, lactoperoxidase, and transforming growth factor β2	≤ 3%	For use as an ingredient in powdered, nonexempt term infant formulas and toddler formulas at levels up to 30 milligrams per 100 gram of powdered formula.	FDA ceased to evaluate in May 2016. Reasons are not specified. GRN 612 appears to be a resubmission of 611.
611	Fractionated whey protein isolate containing cow's milk derived lactoferrin, lactoperoxidase, and transforming growth factor β2	≤ 3%	For use as an ingredient in meal replacement beverages at levels up to 100 milligrams (mg) per serving (240 milliliter) and in medical foods at varying levels so that resulting intake of ingredient does not exceed 610 mg per person per day.	FDA ceased to evaluate in April 2016. Reasons are not specified.
504	Milk protein concentrate and milk protein isolate	Up to 49%	Use as protein sources, emulsifiers, flavoring agents, formulation aids, nutritive sweeteners (for ingredients containing more than 20% lactose), stabilizers, thickeners, humectants, and texturizers in a variety of foods. The notifiers estimated per capita intake of concentrated milk protein to be 0.686 g per person per day (g/p/d). Assuming that all MPC/MPI ingredients are consumed by only 10% of the population, the daily consumption of MPC/MPI would be 6.86 g/p/d.	FDA issued a "no questions" letter in Jun. 2009. GRN 504 is a resubmission of GRN 444

444	Milk protein concentrate and milk protein isolate	Up to 49%	As ingredients in meal replacements and bars, term infant formula, milk products, non-standardized cheese products, confections and frosting, puddings and fillings, and dressings, soups, sauces, and snack foods.	FDA ceased to evaluate in Mar. 2012.
413	Colostral whey protein concentrate	≥ 6.0%	As an ingredient in multiple food categories at a level of either 1 gram or 100 milligrams per serving of food, depending on which of two product formulations is used.	FDA ceased to evaluate in Oct. 2012.
196	Bovine milk basic protein fraction	≤ 2%	As an ingredient in certain foods and beverages at 10 - 40 milligrams per serving.	FDA issued a "no questions" letter in Sep. 2006.
52	Whey mineral concentrate	9.0%	Use in beverages, foods, and dairy products as a source of calcium at levels consistent with current calcium supplementation guidelines.	FDA issued a "no questions" letter in Jan. 2001.
37	Whey protein isolate and dairy product solids	≥ 59%	Use in foods in general. FDA estimates that the current consumption of whey products on a per capita basis is approximately 3.8 grams per person per day (g/p/d) and that the incremental per capita exposure to whey products from the consumption of whey protein isolate and dairy product solids would be approximately 0.2 g/p/d, an increase of 5 percent. FDA estimates that approximately 99 percent of the U.S. population consumes lactose-containing products.(1) In addition, FDA estimates that the current mean consumption of lactose is approximately 16 grams per person per day (g/p/d) and that the current 90th percentile consumption of lactose is approximately 33 g/p/d. FDA also estimates that the incremental consumption of lactose from the consumption of whey protein isolate and dairy product solids would be less than 0.1 g/p/d, an increase of approximately 0.3 percent.	FDA issued a "no questions" letter in Apr. 2000.

It is noted that the composition of the whey permeate and whey defined in 21 C.F.R. §184.1979 is very similar, differing mostly in the level of protein and carbohydrate. Table 6 compares the composition of the whey permeate and whey defined per §184.1979.

Table 6: Composition Comparison of Whey Permeate and Whey defined per 21 C.F.R. §184.1979

Parameter	Whey Permeate	Whey per 21 C.F.R. §184.1979
Protein, %	2.0 - 4.5	10 - 15
Fat, %	0.0 - 0.2	0.2 - 2.0
Carbohydrate (Lactose), %	80.0 - 90.0	61 - 75
Ash, %	6.0 - 9.0	7 - 14
Moisture, %	1.0 - 5.0	1 - 8

In summary, FDA has cleared a variety of whey and whey-related substances for use in food. The composition of whey permeate and GRAS-affirmed whey per 21 C.F.R. §184.1979 is very similar. All of the above support the safety nature of whey permeate.

6.3 Safety of whey permeate

6.3.1. Human consumption of whey permeate

The whey permeate is produced by the removal of protein and fat from milk or whey to the extent practical, resulting in a product with a high concentration of lactose. Milk and products derived from milk, such as whey, have a long history of safe consumption by humans at all ages in the form of fluid milk, in dried form (i.e. milk powder), or as milk-derived ingredients.

6.3.2. Manufacture of whey permeate

The whey permeate is manufactured using safe and well-characterized physical separation techniques, which do not cause substantive alterations to the chemical character and safety related properties of the constituents. The components of the food grade oil-based defoamer used as processing aid throughout the manufacturing process of whey permeate are all either approved ingredients for food or GRAS food ingredients and are used in accordance with food cGMP (21 CFR Part 110). The manufacturing process does not generate, concentrate, or introduce any potential toxicants. As a result, the whey permeate is as safe as whey itself.

6.3.3. Safety studies on whey permeate

Given the long history of human consumption of milk, whey, and related products, the whey permeate is of little toxicological concern to humans or animals. The regulatory clearances by FDA on milk, whey, and related products as listed in Table 4 and 5, as well as the similarity between the whey permeate and GRAS affirmed whey per 21 C.F.R. §184.1979 as shown in Table 6, support the safety of whey permeate. A literature search does not yield any reported adverse effects. Most of the whey permeate is 80.0-90.0% carbohydrate or lactose, which is addressed below. The rest of components are 2.0-4.5% protein, 0.0-0.2% fat, 6.0 - 9.0% ash, and 1.0 - 5.0% moisture. With the exposure of 3.84 g/day or 9.6 g/day of the whey permeate as calculated in Section 3.1, these components are not expected to yield any adverse effects at these levels.

We address lactose intolerance and milk allergenicity below.

6.3.4. Lactose Intolerance

Lactose is a disaccharide of glucose and galactose and the primary sugar of mammalian milk and other dairy products.[3] Lactose intolerance refers to the inability or insufficient ability to digest lactose, caused by the absence or reduced production the required enzyme lactase. Lactase breaks down lactose into two simpler forms of sugar, glucose and galactose, which are then absorbed into the bloodstream. If degradation of lactose does not occur or occurs only partially, the lactose acts as a laxative: increasing water content in lumen, flatulence and abdominal pain. People with lactose intolerance may feel uncomfortable 30 minutes to 2 hours after consuming milk and dairy products. Symptoms range from mild to severe, based on the amount of lactose consumed and the amount a person can tolerate. Common symptoms include abdominal pain, abdominal bloating, gas, diarrhea, and nausea. Symptoms of lactose intolerance have been described after intake of less than 6 g of lactose in some subjects. The vast majority of subjects with lactose maldigestion will tolerate up to 12 g of lactose as a single dose with no or minor symptoms.[4] Higher doses may be tolerated, if distributed throughout the day. Research indicates that most people with lactose intolerance are able to consume the amount of lactose in up to 2 cups of milk a day if taken with meals, one at breakfast and the other at dinner.[5]

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[3] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on lactose thresholds in lactose intolerance and galactosaemia. EFSA Journal 2010;8(9):1777. [29 pp.]. doi:10.2903/j.efsa.2010.1777. Available online: www.efsa.europa.eu/efsajournal.htm

[4] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on lactose thresholds in lactose intolerance and galactosaemia. EFSA Journal 2010;8(9):1777. [29 pp.]. doi:10.2903/j.efsa.2010.1777.
Available online: www.efsa.europa.eu/efsajournal.htm

[5] National Dairy Council, Handbook of Dairy Foods and Nutrition (3rd ed. 2006) (see Chapter 8).

As estimated in the dietary exposure section, we conservatively use the highest consumption value of 48 g/day for "candy containing chocolate" for chocolate intake. When whey permeate is used in chocolate at 8%, the exposure to the whey permeate would be:

48 g/day x 8% = 3.84 g/day

Carbohydrate or lactose is 80.0-90.0% in the whey permeate, the exposure to lactose at the high end would be:

3.84 g/day x 90.0% = 3.46 g/day

If whey permeate is used in chocolate at 20%, the exposure to the whey permeate would be:

48 g/day x 20% = 9.6 g/day

And the highest exposure to lactose would be:

9.6 g/day x 90.0% = 8.64 g/day

Therefore, even with the overly-exaggerated assumptions to estimate the lactose intake from consuming chocolate containing the whey permeate, there is not expected to have a safety concern for the majority of population.

In addition, as shown in Table 4, the lactose content in the whey permeate (80.0 -90.0%) is somewhat higher than that in whey per § 184.1979 (61-75%), reduced lactose whey per § 184.1979a (≤ 60%), and whey protein concentrate per § 184.1979c (maximum 60%), and it is similar to that in reduced minerals whey per § 184.1979b (maximum 85%). These FDA GRAS-affirmed whey and whey products are permitted for use in food in accordance with good manufacturing practice, without limitation. Lactose is also allowed as sweetener in food with no limitations. Therefore, we do not anticipate any unique impact on lactose sensitive populations. Furthermore, the whey permeate will clearly include "milk", "whey" or "dairy" as part of the common or usual name of the ingredient. This will indicate that the product contains lactose and will inform those consumers who have lactose intolerance.

6.3.5. Allergenicity of Milk

Milk is among the eight most common food allergens.[6] The allergy prevalence in the US for milk is about 2.5% in children and 0.3% in adults. Since milk protein is responsible for milk allergy and the whey permeate contains significantly less protein than milk, allergy, if any, produced by the whey permeate is expected to be significantly lower than that by milk when consumed. In addition, the whey permeate will clearly include "milk", "whey" or "dairy" as part of the

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[6] FDA Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food, 2006. https://www.fda.gov/media/78205/download

common or usual name of the ingredient. This will indicate that the product contains milk protein and will inform those consumers who are allergic to milk and satisfy food allergen labeling requirements.

6.4 Discussion and conclusion

Proliant Dairy, LLC. has determined that the whey permeate (VersiLac® Dairy Product Solids) is Generally Recognized as Safe (GRAS) based on the following:

- The whey permeate is manufactured under current good manufacturing practices (cGMP) for food (21 C.F.R. Part 110) and meets appropriate food grade specifications.
- The intended use in chocolate and the estimated consumption of the whey permeate and lactose.
- Existing regulatory clearances and existing GRAS notices on whey, whey-related products and lactose, demonstrating the safe nature of these substances.
- The proper labeling of the products; and
- Supportive evidence from the long history of safety use of milk and whey as food.

In conclusion, based on the documentation provided in this GRAS Notice, and as discussed above, it is concluded that there is reasonable certainty that the whey permeate is safe under the intended conditions of use and is also Generally Recognized as Safe (GRAS), by scientific procedures.

Part 7 – List of supporting data and information

7.1 References

Codex Alimentarius Commission 'Standard for Dairy Permeate Powders' - CXS 331-2017.

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on lactose thresholds in lactose intolerance and galactosaemia. EFSA Journal 2010;8(9):1777. [29 pp.]. doi:10.2903/j.efsa.2010.1777. Available online: www.efsa.europa.eu/efsajournal.htm

FDA Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food, 2006. https://www.fda.gov/media/78205/download

FDA Reference Amounts Customarily Consumed: List of Products for Each Product Category: Guidance for Industry. February 2018. Available online: https://www.fda.gov/media/102587/download

National Dairy Council, Handbook of Dairy Foods and Nutrition (3rd ed. 2006) (see Chapter 8).

Smiciklas-Wright, H., D.C. Mitchell, S.J. Mickle, A.J. Cook, and J.D. Goldman. 2002. Foods Commonly Eaten in the United States: Quantities Consumed Per Eating Occasion and in a Day, 1994-1996. U.S. Department of Agriculture NFS Report No. 96-5, pre-publication version, 252 pp. Available online: www.barc.usda.gov/bhnrc/foodsurvey/Products9496.html.