PRODUCT INFORMATION SHEET

β-Lactoglobulin, Casein, Gluten and Soya in hypoallergenic Infant Food with hydrolysed Milk Protein (negative)

PT originated REFERENCE MATERIAL (RM)

Description of the RM

Name / Material of related PT	*DLA ptAL03 (2024) – Allergens III: β-Lactoglobulin, Casein, Gluten and Soya in hypoallergenic Infant Food with hydrolysed Milk Protein with "Spiking Level Sample“ (3 different Samples) –* ***Sample A*** *(negative sample)*
Identifier / LOT	*RM 2024-AL03 A*
Expiry date	*May 2028*
Matrix	*hypoallergenic Infant Food*
Physical description	*Powder*
Packaging / weight	*Sealed foil pouche / 25 g*
Storage conditions	*2 - 10°C (dry and dark)*
Name and address manufacturer	***DLA - Proficiency Tests GmbH*** *Hauptstr. 80, 23845 Oering, Germany* *Tel. ++49-(0)4532-9183358, Fax. ++49(0)4102-9944976* *eMail. pt@dla-lvu.de, website. www.dla-lvu.de*

Composition of Material

Ingredients	Sample A **present sample**	Sample B	Sample SP
Infant formula with hydrolyzed whey protein, in case of allergy to milk, from birth (powder for preparation, balanced diet) Ingredients: glucose syrup, hydrolyzed whey protein, vegetable oils, maltodextrin, fish oil, vitamins, minerals and other food additives Nutrients per 100 g powder: Fat 25 g, Carbohydrates 54 g, Protein 13 g, Salt 0,4 g	96,2 g/100 g	95,9 g/100 g	-
Casein-Hydrolyzate (Drink powder) Nutrients per 100 g powder: Fat 1,5 g, Carbohydrates 0 g, Protein 81 g, Salt 3,8 g	3,8 g/100g	3,8 g/100g	
Potato Powder Ingredients: Potatoes, E471, E304, E223, E100	-	-	99,7 g/100 g
Milk component 1: **skimmed milk powder** mixture (9 products from Europe, USA) – as skimmed milk powder* – *thereof 33,0% total protein*** – *thereof casein**** – *thereof ß-lactoglobulin****	-	 119 mg/kg 39,2 mg/kg 31,3 mg/kg 3,92 mg/kg	 119 mg/kg 39,4 mg/kg 31,5 mg/kg 3,94 mg/kg
Milk component 2: **whey powder** mixture (4 products from Germany) – as whey powder* – *thereof 15,9% total protein*** – *thereof ß-lactoglobulin****	-	 315 mg/kg 50,1 mg/kg 25,1 mg/kg	 302 mg/kg 48,0 mg/kg 24,0 mg/kg
Sum of milk components – total protein – casein – total β-lactoglobulin	-	434 mg/kg 89,3 mg/kg 31,3 mg/kg 29,0 mg/kg	421 mg/kg 87,4 mg/kg 31,5 mg/kg 27,9 mg/kg
Wheat flour mixture (21 products from Europe, Asia, USA) – as wheat flour* – *thereof 10,1% total protein*** – *thereof gluten****	-	 242 mg/kg 24,4 mg/kg 21,0 mg/kg	 248 mg/kg 25,1 mg/kg 21,6 mg/kg
Soyflour, toasted mixture (6 products from Asia, Europe, USA) – as soya flour* – *thereof 37,8% total protein*** – *calculated soy trypsin inhibitor****	-	 40,7 mg/kg 15,4 mg/kg 2,31 mg/kg	 37,2 mg/kg 14,1 mg/kg 2,12 mg/kg
further Ingredients: *Maltodextrin and silicon dioxide*	-	<0,3 g/100 g	<0,3 g/100g

* Allergen contents as "total food" as described in the column ingredients according to the gravimetric mixture
** Protein contents according to laboratory analysis of the raw material (total nitrogen according to Kjeldahl with F=6,38 for milk protein, F=5,7 for wheat protein and F=5,71 for soya protein)
*** Protein contents according to literature values (approx. 80% casein and 10% β-lactoglobulin in total milk protein; approx. 50% β-lactoglobulin in whey protein; 8,7% gluten in wheat flour and approx. 15% soybean trypsin inhibitor in soy protein)

Note: *The metrological traceability of temperature, mass and volume during the production of the PT samples is ensured by DAkkS-compliant calibrated reference materials.*

Minimum Sample Size / Homogeneity
A minimum sample size of 5 g is recommended for sample preparation.

Reference Values
All reference values were derived from the related PT round (for more details see final report).

Reference Values qualitative ELISA

Parameter	β-Lacto-globulin	Casein	Total Milk protein	Gluten	Soya Protein
Number positive	9	1	2	1	0
Number negative	1	11	2	19	15
Percent positive	90	8	50	5	0
Percent negative	10	92	50	95	100
Consensus value	*positive***	***negative***	*none***	***negative***	***negative***

* Results of diverse ELISA Methods (LODs positive results β-Lactoglobulin 0,0015-10 mg/kg, Casein 0,04-2,5 mg/kg, Total Milk Proten 0,05-1,2 mg/kg, Gluten 0,3-10 mg/kg, Soya Protein 0,016-2,5 mg/kg)
** The sample matrix contains hydrolyzed milk proteins (whey and casein), which are probably the cause of the positive ELISA results.

Reference Values qualitative PCR

Parameter	Soya*
Number positive	1
Number negative	3
Percent positive	25
Percent negative	75
Consensus value	***negative***

* Results of diverse PCR Methods (LODs positive results Soya 0,4-1,25 mg/kg)

Intended Use
- for laboratory use only, no food!
- validation of analytical methods
- control sample for quality control charts
- test material for inter-laboratory comparisons
- no medical use

Storage Instructions and Handling Information
The material should be stored as stated on page 1. Before use of the material should be warmed up to room temperature. The content should be mixed thoroughly prior to subsampling (see minimum sample size above). The material should be weighed immediately after opening of the foil pouche/bottle and closed again afterwards in order to avoid uptake of moisture. Frequent freezing and thawing should be avoided as this can lead to changes in the properties of the material. The expiry date of this RM is based on the current knowledge and applies only for proper storage conditions in the originally closed foil pouche/bottle.

Safety Precautions
The usual laboratory safety precautions should be applied when working with the RM considering the type of ingredients, parameters and its concentration.

Data Source
The material was analyzed by 22 laboratories within the related proficiency test (PT). Different analytical methods have been used.

Various
The user must determine the suitability of this RM for its particular purpose. DLA makes no warranty of any kind, expressed or implied, other than its products meet all quality control standards set by DLA. We do not guarantee this product can be used for a special application.

DLA Proficiency Tests

Datum / Date: 14 April 2025

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- signed U. Vorreiter