

PRODUCT INFORMATION SHEET

**Gluten (Wheat) and
Milk (β -Lactoglobulin, Casein)
in Infant Food (Cereal Pap with Fruit Powder) (positive)
PT originated REFERENCE MATERIAL (RM)**

Description of the RM

Name / Material of related PT	DLA ptAL03 (2025) – Allergens III: Gluten (Wheat) and Milk (β -Lactoglobulin, Casein) in Infant Food (Cereal Pap with Fruit Powder) with "Spiking Level Sample" (3 different Samples) – Sample B (positive sample)
Identifier / LOT	RM 2025-AL03 B
Expiry date	July 2029
Matrix	Cereal Pap with Fruit Powder
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	Sample B present sample	Sample SP
Millet Pap Powder, organic Ingredients: Wholemeal millet flour, thiamine Nutrients per 100 g: Fat 4,0 g, Carbohydrates 76 g, Protein 12 g	44,4 g/100 g	44,3 g/100 g	-
Rice Pap Powder, organic Ingredients: Rice flour, thiamine Nutrients per 100 g: Fat 0,7 g, Carbohydrates 85 g, Protein 7,3 g	40,8 g/100 g	40,7 g/100 g	-
Strawberry Powder Ingredients: Strawberries, freeze-dried Nutrients per 100 g: Fat 1,4 g, Carbohydrates 84 g, Protein 5,3 g and positive sample : allergenic ingredients as below	14,8 g/100 g	14,7 g/100 g	-
Potato Powder Ingredients: Potatoes, E471, E304, E223, E100	-	-	99,8 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 β -lactoglobulin***		83,8 mg/kg 27,7 mg/kg 22,1 mg/kg 2,77 mg/kg	86,0 mg/kg 28,4 mg/kg 22,7 mg/kg 2,84 mg/kg
Milk component 2: whey powder mixture (4 products from Germany) – as whey powder* – thereof 15,9% total protein** – thereof β -lactoglobulin***	-	324 mg/kg 51,4 mg/kg 25,7 mg/kg	321 mg/kg 51,1 mg/kg 25,6 mg/kg
Sum of milk components – total protein – casein – total β -lactoglobulin	-	408 mg/kg 79,1 mg/kg 22,1 mg/kg 28,5 mg/kg	407 mg/kg 79,5 mg/kg 22,7 mg/kg 28,4 mg/kg
wheat flour mixture (21 products from Europe, Asia, USA) – as wheat flour* – thereof 10,1% total protein** – thereof gluten***	-	358 mg/kg 36,1 mg/kg 31,1 mg/kg	352 mg/kg 35,5 mg/kg 30,6 mg/kg
further Ingredients: Maltodextrin and silicon dioxide	-	<0,2 g/100 g	<0,2 g/100 g

* 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 and F=5,7 for wheat 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 and 8,7% gluten in wheat flour)

Note: The metrological traceability of temperature, mass and volume during 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.

The homogeneity tests were performed with sample sizes of 5 g (Microtracer analysis) and 1 - 5 g (ELISA methods), respectively.

The mixture homogeneity was examined 10-fold by microtracer analysis. Homogeneity was sufficient with a probability of $\geq 25\%$ (excellent mixture) and a HorRat value in the range of acceptance (0,3 to 1,3). The homogeneity tests of the β -Lactoglobulin, Casein and Gluten were carried out by ELISA analyzing two subsets from 10 test items (according to ISO 13528:2015 Annex B). Homogeneity was sufficient with a standard deviation between the samples S_s of $\leq 15\%$ („heterogeneity standard deviation“) using ELISA test kits from different manufacturers, e.g. AgraQuant Allergen ELISA Romer Labs, GSD Allergen ELISA Gold Standard Diagnostics Kassel, Morinaga Food Allergen ELISA Kits MloBS, Veratox ELISA for Food Allergens Neogen (for more details see final report of PT).

Reference Values

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

Reference Values quantitative in mg/kg ELISA

Parameter	β -Lactoglobulin		Casein
	All Results (Info)*	Method RS-F**	All results* (Info)
Number of results	15	5	19
Number of outliers	0	0	0
Assigned Value (Xpt)	12,6	18,3	14,2
Robust standard deviation	7,77	7,94	8,77
Standard uncertainty	2,51	4,44	2,51
Target standard deviation opt	3,15	4,58	3,55
Target range	6,3 – 18,9	9,16 – 27,5	7,10 – 21,3

* ELISA Method: divers Methods

** ELISA Method: RS-F= Ridascreen® Fast, R-Biopharm

(Info): for information only

Parameter	Milk proteins, total		
	Group 1*	Group 2**	Method RS-F***
Number of results	9	7°	6°
Number of outliers	0	1	1
Assigned Value (Xpt)	32,3	118	112
Robust standard deviation	17,4	41,0	33,2
Standard uncertainty	7,27	19,4	16,9
Target standard deviation opt	8,08	29,5	27,9
Target range	16,2 – 48,5	58,9 - 117	55,8 - 167

* ELISA Methods: Group 1: AQ = AgraQuant, RomerLabs, ES = ELISA Systems, GSD = Gold Standard Diagnostics, Kassel, SP = SensiSpec, Gold Standard Diagnostics, VT = Veratox, Neogen

** ELISA Methods: Group 2: IFP = ELISA-Fast, ifp, RS-F= Ridascreen® Fast, R-Biopharm

*** ELISA Method: RS-F= Ridascreen® Fast, R-Biopharm

° without outlier

Parameter	Gluten	
	All Results*	Method RS**
Number of results	27	18
Number of outliers	0	0
Assigned Value (Xpt)	26,5	24,9
Robust standard deviation	11,2	8,67
Standard uncertainty	2,69	2,55
Target standard deviation opt	6,62	6,23
Target range	13,2 – 39,7	12,5 – 37,4

* ELISA Method: divers Methods

** ELISA Method: RS = Ridascreen®, R-Biopharm

Reference Values qualitative ELISA

Parameter	β-Lactoglobulin*	Casein*	Milk proteins, total*	Gluten*
Number positive	16	20	19	29
Number negative	0	1	0	1
Percent positive	100	95	100	97
Percent negative	0	5	0	3
Consensus value	positive	positive	positive	positive

* Results of diverse ELISA Methods (LODs positive results β-Lactoglobulin 0,002-0,167 mg/kg, Casein 0,04-2,5 mg/kg, Total Milk Protein 0,05-5,0 mg/kg, Gluten 0,3-5,0 mg/kg)

Reference Values qualitative PCR

Parameter	Wheat and Gluten containing Cereals*
Number positive	3
Number negative	1
Percent positive	75
Percent negative	25
Consensus value	positive

* Results of diverse PCR Methods (LODs positive results Gluten containing Cereal 0,4-1000 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 poche/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 poche/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 35 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.



approved (PT-Coordinator)	updated
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