PRODUCT INFORMATION SHEET

Gluten (Spelt Wheat, Triticum spelta) and Milk (β-Lactoglobulin, Casein) in Infant Food (Soy Formula) (positive)

PT originated REFERENCE MATERIAL (RM)

Description of the RM

Name / Material of related PT	*DLA ptAL03 (2026) – Allergens III: Gluten (Spelt Wheat, Triticum spelta) and Milk (β-Lactoglobulin, Casein) in Infant Food (Soy Formula) [Samples A + B] and "Spiking Level Sample" [SP] (3 different Samples) –* ***Sample A*** *(positive sample)*
Identifier / LOT	*RM 2026-AL03 A*
Expiry date	*June 2027*
Matrix	*Infant Food (Soy Formula)*
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 Soy Formula, "dairy free" (from birth) **(for dietary management in cow's milk allergy or intolerance)** Ingredients: maltodextrin, vegetable oils, soy protein isolate, vitamins, minerals, amino acids and other food additives and **positive sample:** allergenic ingredients as below Nutrients per 100 g powder: Fat 23 g, Carbohydrates 58 g, Protein 11 g, Salt 0,5 g	99,8 g/100 g	100 g/100 g	-
Potato Powder Ingredients: Potatoes, E471, E304, E223, E100	-	-	99,8 g/100 g
***Spelt Wheat,* flour,** 1 product from Germany		-	
– as spelt wheat flour*	500 mg/kg		524 mg/kg
– *thereof 12,4% total protein***	62,0 mg/kg		64,9 mg/kg
– *calculated as gluten****	45,9 mg/kg		48,1 mg/kg
Milk Component 1:		-	
skimmed milk powder mixture (9 products from Europe, USA)			
– as skimmed milk powder*	80,4 mg/kg		79,7 mg/kg
– *thereof 33,0% total protein***	26,5 mg/kg		26,3 mg/kg
– *thereof casein****	21,2 mg/kg		21,0 mg/kg
– *thereof β-lactoglobulin****	2,65 mg/kg		2,63 mg/kg
Milk Component 2:		-	
whey powder mixture (4 products from Germany)			
– as whey powder*	131 mg/kg		137 mg/kg
– *thereof 15,9% total protein***	20,9 mg/kg		21,9 mg/kg
– *thereof β-lactoglobulin****	10,5 mg/kg		10,9 mg/kg
Sum of Milk Components	212 mg/kg	-	217 mg/kg
– total protein	47,5 mg/kg		48,2 mg/kg
– casein	21,2 mg/kg		21,0 mg/kg
– total β-lactoglobulin	13,1 mg/kg		13,6 mg/kg
further Ingredients: Maltodextrin, sodium sulfate and silicon dioxide	<0,3 g/100 g	-	<0,3 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=5,83 for spelt wheat protein and F=6,38 for milk protein)
*** Protein contents according to literature values (approx. 80% casein and 10% β-lactoglobulin in total milk protein [A]; approx. 50% β-lactoglobulin in whey protein [A] and gluten content in wheat protein 74% according to: AOAC guidelines for validation of quantitative gluten methods, Annex B [B, C, D]

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 ≥ 25% (excellent mixture) and a HorRat value in the range of acceptance (0,3 to 1,3). The homogeneity tests of the parameter Casein were carried out by ELISA analyzing two subsets from 10 test items (according to ISO 13528:2022 Annex B). Homogeneity was sufficient with a standard deviation between the samples Ss of ≤ 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 Morinaga BioScience, Inc. (for more details see final report of PT).

Reference Values
All reference values were derived from the related ISO 17043 accredited PT round (for more details see final report).

Reference Values quantitative in mg/kg ELISA

Parameter	**Gluten**		**β-Lactoglobulin**	
	All Results*	Method RS**	All Results* (Info)	Method RS-F***
Number of results	17	12	11	6
Number of outliers	-	-	-	-
Assigned Value (Xpt)	***61,9***	***63,4***	***4,79***	***5,81***
Robust standard deviation	17,1	13,8	1,97	1,22
Standard uncertainty	5,19	4,99	0,742	0,625
Target standard deviation σpt	15,5	15,8	1,20	1,45
Target range	***30,9 – 92,8***	***31,7 – 95,0***	***2,40 – 7,19***	***2,90 – 8,71***

* ELISA Method: divers Methods
** ELISA Method: RS = Ridascreen®, R-Biopharm
*** ELISA Method: RS-F= Ridascreen® Fast, R-Biopharm
(Info): for information only

Parameter	**Casein**	
	All Results (Info)*	Method RS-F**
Number of results	13°	9
Number of outliers	3	-
Assigned Value (Xpt)	***4,98***	***4,52***
Robust standard deviation	2,01	1,70
Standard uncertainty	0,695	0,708
Target standard deviation σpt	1,25	1,13
Target range	***2,49 – 7,47***	***2,26 – 6,77***

* ELISA Method: divers Methods
** ELISA Method: RS-F= Ridascreen® Fast, R-Biopharm
° without outlier
(Info): for information only

Parameter	**Milk Proteins, Total**		
	"Group 1" (Info)	"Group 2" **	Method RS-F***
Number of results	4	8	6
Number of outliers	-	-	-
Assigned Value (Xpt)	***15,0***	***61,7***	***60,0***
Robust standard deviation	1,02	8,28	8,21
Standard uncertainty	0,638	3,66	4,19
Target standard deviation σpt	3,75	15,4	15,0
Target range	***7,50 – 22,5***	***30,9 – 92,6***	***30,0 – 90,0***

* ELISA Method: "Group 1" Methods: AQ = AgraQuant, RomerLabs, SP = SensiSpec ELISA Kit, Gold Standard Diagnostics, VT = Veratox, Neogen
** ELISA Method: "Group 2" Methods: AQ-P = AgraQuant Plus, RomerLabs, IFP = ELISA-Fast, ifp, RS-F= Ridascreen® Fast, R-Biopharm
*** ELISA Method: RS-F = R-Biopharm, Ridascreen Fast
(Info): for information only

Reference Values qualitative ELISA

Parameter	**Gluten***	**β-Lactoglobulin***	**Casein***	**Milk Proteins, Total***
Number positive	19	15	17	13
Number negative	0	0	1	0
Percent positive	100	100	94	100
Percent negative	0	0	6	0
Consensus value	***positive***	***positive***	***positive***	***positive***

* Results of diverse ELISA Methods (LODs are in the common range of the applied ELISA Testkits, for specific values see final report)

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, 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 24 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.

created	approved (PT-Coordinator)	updated
Ulrike Vorreiter	Matthias Besler-Scharf, PhD	-
signed U. Vorreiter	*signed M. Besler-Scharf*	-
18 June 2026	19 June 2026	-