

PRODUCT INFORMATION SHEET

Gluten (Wheat), Pistachio and Soya in Boiled Sausage (positive)

PT originated REFERENCE MATERIAL (RM)

Description of the RM

Name / Material of related PT	<i>DLA ptAL02 (2025) – Allergens II: Gluten (Wheat), Pistachio and Soya in Boiled Sausage with "Spiking Level Sample" (3 different Samples) – Sample B (positive sample)</i>
Identifier / LOT	<i>RM 2025-AL02 B</i>
Expiry date	<i>June 2029</i>
Matrix	<i>Boiled Sausage</i>
Physical description	<i>Solid paste-like</i>
Packaging / weight	<i>Screw-cap jars / 25 g</i>
Storage conditions	<i>< -18°C (dry and dark)</i>
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
Boiled Sausage (100°C, 60 min) Ingredients: Minced meat (beef and pork) 70%, water 25%, pork gelatine 3,4%, salt 0,3%, citric acid, sorbic acid and positive sample: allergenic ingredients as below	100,0 g/100 g	99,5 g/100 g	-
Potato Powder Ingredients: Potatoes, E471, E304, E223, E100	-	-	99,9 g/100 g
Wheat flour, mixture (21 products from Europe, Asia, USA) – as wheat flour* – thereof 10,1% total protein** – calculated as gluten***	-	364 mg/kg 36,8 mg/kg 31,7 mg/kg	435 mg/kg 43,9 mg/kg 37,9 mg/kg
Pistachio, roasted, milled mixture (10 products from USA, Iran, Turkey, Greece, Italy, Spain) – as pistachio* – thereof 21,1% total protein**	-	189 mg/kg 39,9 mg/kg	40,1 mg/kg 8,45 mg/kg
Soya flour, toasted mixture (6 products from Asia, Europe, USA) – as soya flour* – thereof 37,8% total protein** – calculated soy trypsin inhibitor***	-	94,8 mg/kg 35,9 mg/kg 5,38 mg/kg	58,1 mg/kg 22,0 mg/kg 3,30 mg/kg
<i>further Ingredients: Maltodextrin, sodium sulfate and silicon dioxide</i>	-	<0,5 g/100 g	<0,1 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=5,7 for wheat protein, F=5,30 for pistachio protein and F=5,71 for soya protein)

*** Protein contents according to literature values (approx. 8,7% gluten in wheat flour; approx. 15% soybean trypsin inhibitor in soy protein)

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 of Gluten, Pistachio and Soya 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	Gluten		Pistachio
	All Results*	Method RS**	All Results*
Number of results	30	17	7
Number of outliers	-	-	-
Assigned Value (Xpt)	31,7	33,7	2,70
Robust standard deviation	7,95	5,23	0,716
Standard uncertainty	1,82	1,58	0,338
Target standard deviation opt	7,92	8,42	0,675
Target range	15,8 – 47,5	16,8 – 50,5	1,35 – 4,05

* ELISA Method: divers Methods (Pistachio: no results from method BF Biofront available)

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

Parameter	Total Soya Protein*	
	All Results*	Method RS-F**
Number of results	13°	10°
Number of outliers	3	3
Assigned Value (Xpt)	15,0	16,3
Robust standard deviation	4,48	4,26
Standard uncertainty	1,55	1,68
Target standard deviation opt	5,56	4,08
Target range	7,48 – 22,4	8,17 – 24,5

* ELISA Method: divers Methods

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

° without outlier

Reference Values qualitative ELISA

Parameter	Gluten*	Pistachio*	Total Soya Protein*
Number positive	30	7	17
Number negative	1	2	3
Percent positive	100	78	85
Percent negative	0	22	15
Consensus value	positive	positive	positive

* Results of diverse ELISA Methods (LODs positive results Gluten 0,4-10 mg/kg, Pistachio 0,13-1,0 mg/kg, Total Soya Protein 0,24-2,5 mg/kg)

Reference Values qualitative PCR

Parameter	Wheat Flour*	Pistachio*	Soya*
Number positive	6	12	15
Number negative	0	0	0
Percent positive	100	100	100
Percent negative	0	0	0
Consensus value	positive	positive	positive

* Results of diverse PCR Methods (LODs positive results Wheat 0,4-20 mg/kg, Pistachio 0,4 mg/kg, Soya 0,5-20 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 31 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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