

PRODUCT INFORMATION SHEET
**Gluten (Wheat), Mustard and Soya
in Oat Flour (positive)**
PT originated REFERENCE MATERIAL (RM)

Description of the RM

Name / Material of related PT	DLA ptAL11 (2025) – Allergens XI: Gluten (Wheat), Mustard and Soya in Oat Flour and Rice Flour – Sample B (positive sample)
Identifier / LOT	RM 2025-AL11 B
Expiry date	October 2026
Matrix	Oat Flour
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 C	Sample D
Oat Flour, organic Ingredients: Oat flour positive sample: allergenic ingredients as below Nutrients per 100 g: Fat 6,7 g, Carbohydrates 60 g, Protein 13 g	100 g/100 g	> 99,8 g/100 g	-	-
Rape seed Seeds, ground – as rape seed* – thereof 17,8 % total protein**	22,4 mg/kg 3,99 mg/kg	22,4 mg/kg 3,99 mg/kg	-	-
Rice Flour, organic Ingredients: Long grain rice, parboiled positive sample: allergenic ingredients as below Nutrients per 100 g: Fat 1,0 g, Carbohydrates 81 g, Protein 8,0 g	-	-	100 g/100 g	> 99,8 g/100 g
Mustard, yellow (<i>Sinapis alba</i>) Seeds, ground, mixture of 9 products (Europe, Asia) – as mustard* – thereof 30,7% total protein**	-	44,9 mg/kg 13,8 mg/kg	-	42,5 mg/kg 13,1 mg/kg
Soya Soyflour, toasted mixture (6 products from Asia, Europe, USA) – as soya flour* – thereof 37,8% total protein** – calculated soy trypsin inhibitor***	-	45,8 mg/kg 17,3 mg/kg 2,60 mg/kg	-	43,4 mg/kg 16,4 mg/kg 2,46 mg/kg
Wheat Wheat flour mixture (21 products from Europe, Asia, USA) – as wheat flour* – thereof 10,1% total protein** – calculated as gluten***	-	485 mg/kg 49,0 mg/kg 42,2 mg/kg	-	434 mg/kg 43,8 mg/kg 37,8 mg/kg
further Ingredients: <i>Maltodextrin and silicon dioxide</i>	<0,1 g/100 g	<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=6,25 for rape seed and mustard protein, F=5,71 for soya protein and F=5,7 for wheat 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 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 parameters Gluten, Mustard 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	
	All Results*	Method RS**
Number of results	35	24
Number of outliers	-	-
Assigned Value (X_{pt})	73,0	68,5
Robust standard deviation	25,8	16,9
Standard uncertainty	5,46	4,32
Target standard deviation σ_{pt}	18,3	17,1
Target range	36,5 – 110	34,4 - 103

* ELISA Method: divers Methods

** ELISA Method: RS = Ridascree®n®, R-Biopharm

Parameter	Mustard			
	All Results (Info)*	Method RS-E (Info)**	Method SP (Info)***	Method VT (Info)****
Number of results	19	4	3	4
Number of outliers	-	-	-	-
Assigned Value (X_{pt})	71,7	53,2	70,0	103
Robust standard deviation	28,0	10,1	20,3	29,4
Standard uncertainty	8,04	6,33	14,6	18,4
Target standard deviation σ_{pt}	17,9	13,3	17,5	25,8
Target range	35,9 - 108	26,6 – 79,8	35,0 - 105	51,6 - 155

* ELISA Method: divers Methods

** ELISA Method: RS-E = Ridascree®n® Easy, R-Biopharm

*** ELISA Method: SP = SensiSpec ELISA Kit, Eurofins

**** ELISA Method: VT = Veratox, Neogen

(Info): for information only

Parameter	Soya Protein			
	All Methods TP*	All Methods STI**	Method RS-F***	Method VT****
Number of results	24°	5	11	5
Number of outliers	1	-	-	-
Assigned Value (Xpt)	13,1	2,77	15,0	9,45
Robust standard deviation	6,00	0,400	5,40	2,32
Standard uncertainty	1,53	0,224	2,03	1,30
Target standard deviation opt	3,26	0,692	3,75	2,36
Target range	6,53 – 19,6	1,38 – 4,15	7,50 – 22,5	4,72 – 14,2

* ELISA Methods: TP = ELISA methods specific for total soy protein (ES = ELISA-Systems, BF = MonoTrace ELISA, BioFront Technologies, MI-II = Morinaga Institute ELISA Kit II, PB = Allergen-Shield ELISA, ProGnosis Biotech, RS-F= Ridascreen® Fast, R-Biopharm, SP-TP =SP-TP = SensiSpec ELISA Total Soy Protein Kit, VT = Veratox, Neogen)

** ELISA Methods: STI = ELISA methods specific for Soy Trypsin Inhibitor (AQ = AgraQuant, RomerLabs, NL-E = nutrilinia®E Allergen-ELISA, SP = SensiSpec ELISA Kit, Gold Standard Diagnostics)

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

**** ELISA Method: VT = Veratox, Neogen

° without outlier

Reference Values qualitative ELISA

Parameter	Gluten*	Mustard*	Soya Protein*
Number positive	39	22	33
Number negative	0	0	0
Percent positive	100	100	100
Percent negative	0	0	0
Consensus value	positive	positive	positive

* Results of diverse ELISA Methods (LODs positive results Gluten 0,36-5,0 mg/kg, Mustard 0,1-2,0 mg/kg, Soya 0,16-2,5 mg/kg)

Reference Values quantitative PCR

Parameter	Mustard	Soya (Info)
Number of results	6°	5
Number of outliers	1	-
Assigned Value (Xpt)	30,5	46,9
Robust standard deviation	11,8	31,8
Standard uncertainty	6,02	17,8
Target standard deviation opt	7,62	11,7
Target range	15,2 – 45,7	23,5 – 70,4

° without outlier / (Info): for information only

Reference Values qualitative PCR

Parameter	Gluten containing-Cereals*	Mustard*	Soya*
Number positive	6	23	15
Number negative	1	0	1
Percent positive	86	100	94
Percent negative	14	0	6
Consensus value	positive	positive	positive

* Results of diverse PCR Methods (LODs positive results Gluten 0,4 mg/kg, Mustard 0,4-4 mg/kg, Soya 0,4-10 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 38 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.



Date: 11 November 2025

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