

PRODUCT INFORMATION SHEET

Gluten, Mustard and Soya in Oat Flour (positive)

PT originated REFERENCE MATERIAL (RM)

Description of the RM

Name / Material of related PT	<i>DLA ptAL11 (2023) Allergens XI: Gluten, Mustard and Soya in Oat Flour and Rice Flour - Sample B</i>
Identifier / LOT	<i>RM 2023-AL11 B</i>
Expiry date	<i>October 2027</i>
Matrix	<i>Oat Flour</i>
Physical description	<i>Powder</i>
Packaging / weight	<i>Sealed foil pouche / 25 g</i>
Storage conditions	<i>cooled 2 - 10°C, long term frozen < -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	Amounts
Oat Flour, organic Ingredients: Oat flour Nutrients per 100 g: Fat 6,7 g, Carbohydrates 60 g, Protein 13 g	>99,9 g/100 g
Rape seed Seeds, ground – as rape seed* – thereof 17,8 % total protein**	18,3 mg/kg 3,26 mg/kg
Mustard, yellow (<i>Sinapis alba</i>) Seeds, ground, mixture of 9 products (Europe, Asia) – as mustard* – thereof 30,7% total protein**	19,2 mg/kg 5,89 mg/kg
Soya Soyflour, toasted mixture (6 products from Asia, Europe, USA) – as soya flour* – thereof 37,8% total protein** – calculated soy trypsin inhibitor***	26,0 mg/kg 9,83 mg/kg 1,47 mg/kg
Wheat Wheat flour mixture (21 products from Europe, Asia, USA) – as wheat flour* – thereof 10,1% total protein** – calculated as gluten***	200 mg/kg 20,2 mg/kg 17,4 mg/kg
further Ingredients: <i>Maltodextrin, sodium sulfate and silicon dioxide</i>	<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 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)

Minimum Sample Size

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 before bottling 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 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“) (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		Soya (as Soya Protein)	
	All methods*	Method RS**	All methods*	Method RS-F***
Number of results	25	15	22	11
Number of outliers	-	-	-	-
Assigned Value (X_{pt})	25,8	24,1	6,58	7,75
Robust standard deviation	8,18	7,99	3,30	2,44
Standard uncertainty	2,05	2,58	0,88	0,920
Target standard deviation σ_{pt}	6,46	6,02	1,65	1,94
Target range	12,9 – 38,7	12,0 – 36,1	3,29 – 9,88	3,88 – 11,6

* Results of diverse ELISA Methods / ** ELISA Method: Ridascreen®, R-Biopharm /

*** ELISA Method: Ridascreen® Fast, R-Biopharm

Parameter	Mustard °	
	All methods*	Method VT**
Number of results	8	5
Number of outliers	-	-
Assigned Value (X_{pt})	49,9	88,5
Robust standard deviation	11,4	33,3
Standard uncertainty	5,02	18,6
Target standard deviation σ_{pt}	12,5	22,1
Target range	25,0 – 74,9	44,3 – 133

* Results of diverse ELISA Methods except method VT / ** ELISA Method: Veratox, Neogen

° Matrix contains rape seed cross-reactive in most ELISA methods

Reference Values qualitative ELISA

Parameter	Gluten *	Mustard	Soya (as Soya Protein) *
Number positive	26	17	23
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 0,3-10 mg/kg gluten, 0,25-2,5 mg/kg mustard and 0,24-2,5 mg/kg soya protein)

Reference Values qualitative PCR

Parameter	Gluten (as Gluten-containing Cereals/Wheat) *	Mustard	Soya *
Number positive	4**	10	12
Number negative	0	2	0
Percent positive	100	83	100
Percent negative	0	17	0
Consensus value	positive	positive	positive

* Results of diverse PCR Methods (LODs 0,4-1 mg/kg gluten-containing cereals / wheat, 0,4-4 mg/kg mustard and 0,4-4 mg/kg soya)

** thereof 2 positive results for cereals including oat

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 28 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.

Datum / Date: 4 November 2024

Dr. Matthias Besler-Scharf (EP-Koordinator / PT-Coordinator)
- *gezeichnet / signed M. Besler-Scharf*

