PRODUCT INFORMATION SHEET

Gluten, Mustard and Soya in Corn Flour (positive)

PT originated REFERENCE MATERIAL (RM)

Description of the RM

Name / Material of related PT	*DLA ptAL11 (2024) – Allergens XI:* ***Gluten, Mustard and Soya in Oat Flour and Corn Flour*** *–* ***Sample D*** *(positive sample)*
Identifier / LOT	*RM 2024-AL11 D*
Expiry date	*November 2028*
Matrix	*Corn 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 C	**Sample D** **present sample**
Corn Flour **positive sample:** allergenic ingredients as below Nutrients per 100 g: Fat 2,8 g, Carbohydrates 66 g, Protein 8,7 g	100 g/100 g	> 99,9 g/100 g
Mustard, yellow (Sinapis alba) **Seeds, ground, mixture** of 9 products (Europe, Asia) – as mustard* – *thereof 30,7% total protein***	 -	 21,1 mg/kg 6,50 mg/kg
Soya **Soyflour, toasted, mixture** (6 products from Asia, Europe, USA) – as soya flour* – *thereof 37,8% total protein*** – *calculated soy trypsin inhibitor****	 -	 28,8 mg/kg 10,9 mg/kg 1,64 mg/kg
Wheat **Wheat flour, mixture** (21 products from Europe, Asia, USA) – as wheat flour* – *thereof 10,1% total protein*** – *calculated as gluten****	 -	 272 mg/kg 27,5 mg/kg 23,7 mg/kg
further Ingredients: *Maltodextrin and silicon dioxide*	 -	 <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 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 ≥ 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 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 MIoBS, 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**		**Mustard**	
	All Results*	Method RS**	All Results*	Method RS-E***
Number of results	38	24	19°	8
Number of outliers	-	-	3	-
Assigned Value (Xpt)	***34,0***	***33,8***	***24,9***	***22,4***
Robust standard deviation	7,37	7,77	4,94	3,43
Standard uncertainty	1,49	1,98	1,42	1,52
Target standard deviation σpt	8,51	8,44	6,24	5,60
Target range	***17,0 – 51,1***	***16,9 – 50,7***	***12,5 – 37,4***	***11,2 – 33,6***

* ELISA Method: divers Methods
** ELISA Method: RS = Ridascreen®, R-Biopharm
*** ELISA Method: RS-E = RS-E = Ridascreen® Easy, R-Biopharm
° without outlier

Parameter	**Soya Protein**		
	All Methods TP*	All Methods STI**	Method RS-F***
Number of results	21	9	14
Number of outliers	-	1	-
Assigned Value (Xpt)	***9,72***	***1,84***	***10,3***
Robust standard deviation	2,66	0,365	1,69
Standard uncertainty	0,726	0,152	0,566
Target standard deviation σpt	2,43	0,560	2,58
Target range	***4,86 – 14,6***	***0,920 – 2,76***	***5,15 – 15,5***

* ELISA Methods TP: specific for Total Soya Protein
** ELISA Methods STI: specific for Soya Trypsin Inhibitor
*** ELISA MethodRS-F= Ridascreen® Fast, R-Biopharm

Reference Values qualitative ELISA

Parameter	Gluten*	Mustard*	Soya Protein*
Number positive	41	26	31
Number negative	1	0	0
Percent positive	98	100	100
Percent negative	2	0	0
Consensus value	***positive***	***positive***	***positive***

* Results of diverse ELISA Methods (LODs positive results Gluten 0,6-10 mg/kg, Mustard 0,5-1 mg/kg, Soya Protein 0,7-2,5 mg/kg)

Reference Values quantitative PCR

Parameter	Mustard (Info)*	Soya (Info)*
Number of results	7	7
Number of outliers	-	-
Assigned Value (Xpt)	***30,8***	***40,3***
Robust standard deviation	28,0	43,6
Standard uncertainty	13,2	20,6
Target standard deviation σpt	7,69	10,08
Target range	***15,4 – 46,2***	***20,15 – 60,5***

* (Info): for information only

Reference Values qualitative PCR

Parameter	Gluten-containing Cereals / Wheat*	Mustard*	Soya*
Number positive	9	18	16
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: Gluten-containing Cereals / Wheat 0,4-10 mg/kg, Mustard 0,4-10 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 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 46 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.

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