PRODUCT INFORMATION SHEET

Allergens Lupine, Black Sesame and Wheat (Gluten) Spiking Level Sample

PT originated REFERENCE MATERIAL (RM)

Description of the RM

Name / Material of related PT	*DLA ptAL02 (2023) Allergens II : Lupine, Black Sesame and Wheat (Gluten) in "gluten-free" Rice Cracker (baked) - Spiking Level Sample*
Identifier / LOT	*RM 2023-AL02 SP*
Expiry date	*May 2027*
Matrix	*Potato Powder*
Physical description	*Powder*
Packaging / weight	*Sealed foil pouche / 15 g*
Storage conditions	*cooled 2 - 10°C, long term frozen < -18°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	**Amounts**
Potato Powder Ingredients: Potatoes, E471, E304, E223, E100	99,9 g/100 g
Lupine Sweet lupine flour, mixture (4 products, Europe) – as lupine flour* – *thereof 38,6% total protein***	 18,5 mg/kg 7,13 mg/kg
Sesame, black (Sesamum indicum nigrum) ground, mixture (6 products, Asia) – as Sesame seed* – *thereof 21,1% total protein***	 16,6 mg/kg 3,49 mg/kg
Wheat Wheat flour mixture (21 products from Europe, Asia, USA) – as wheat flour* – *thereof 10,1% total protein*** – *calculated as gluten****	 205 mg/kg 20,7 mg/kg 17,8 mg/kg
further Ingredients: *Maltodextrin, sodium sulfate and silicon dioxide*	<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=6,25 for lupine protein and sesame protein and F=5,7 for wheat protein)

*** Protein contents according to literature values (8,7% gluten in wheat flour)

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).
The mixture homogeneity before bottling 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) (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	Lupine (as total food item)
	All methods*
Number of results	8
Number of outliers	0
Assigned Value (Xpt)	***20,3***
Robust standard deviation	3,21
Standard uncertainty	1,42
Target standard deviation σpt	5,08
Target range	***10,2 – 30,5***

* Results of diverse ELISA Methods

Parameter	Sesame (as total food item)	
	All methods* (informative only)	Method RS-F** (informative only)
Number of results	4	4
Number of outliers	0	0
Assigned Value (Xpt)	***14,0***	***41,3***
Robust standard deviation	0,679	18,8
Standard uncertainty	0,424	11,7
Target standard deviation σpt	3,51	10,3
Target range	***7,01 – 21,0***	***20,6 – 61,9***

* Results of diverse ELISA Methods (without method RS-F)
** ELISA Method: Ridascreen® Fast, R-Biopharm

Parameter	Wheat Gluten (as gluten)	
	All methods*	Method RS-F**
Number of results	14	11
Number of outliers	-	0
Assigned Value (Xpt)	***29,4***	***28,5***
Robust standard deviation	4,83	4,44
Standard uncertainty	1,61	1,67
Target standard deviation σpt	7,34	7,11
Target range	***14,7 – 44,0***	***14,2 – 42,7***

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

Reference Values qualitative PCR

Parameter	Lupine *	Sesame*	Wheat / Gluten-containing Cereals*
Number positive	8	7	3
Number negative	0	0	0
Percent positive	100	100	100
Percent negative	0	0	0
Consensus value	***positive***	***positive***	***positive***

* Results of diverse Lupine PCR Methods (LODs 0,4-10 mg/kg), Sesame PCR Methods (LODs 0,4-5,5 mg/kg) and Wheat PCR Methods (LODs 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 19 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: 14 May 2024

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

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