

PRODUCT INFORMATION SHEET

Crustaceae, Egg, Fish, Milk, Molluscs, Mustard (yellow/white, brown and black) and Soya (4 Samples qualitative - Detection of "Action Levels" included)

PT originated REFERENCE MATERIAL (RM)

Description of the RM

Name / Material of related PT	DLA ptALS2 (2026) Allergen Screening II - 4 Samples qualitative: Crustaceae, Egg, Fish, Milk, Molluscs, Mustard (yellow/white, brown and black) and Soya - Samples 1-4
Identifier / LOT	RM 2026-ALS2 Set
Expiry date	September 2027
Matrix	Allergens in simple matrix (see tables)
Physical description	Powder
Packaging / weight	Sealed foile poche / 20 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

Assigned values and uncertainties of 2/3 and 1/6 "action levels":

The "action level" in mg/kg is calculated from the allergen protein reference dose per 100 g food portion (based on FAO/WHO 2022 and Vital 4.0 2024 (for more details see final report)). The contents of the allergenic items in the PT-samples 1-4 were gravimetrically adjusted to 2/3 and 1/6 of the "action levels" (s. Tab. 2).

Each assigned value, here the spiked allergen-contents, is afflicted with a standard uncertainty. As uncertainties the following factors were considered: gravimetric weighing, protein contents, homogeneity and stability of allergen protein.

All uncertainties were expressed in the form of their standard deviations and then added as variances. The square root from the sum of the total variances results in the combined uncertainty "Uc". Multiplied with the coverage factor k=2 the extended uncertainties of the assigned values " $U(X_{pt})$ " are obtained (for more details see final report).

For all parameters the extended combined uncertainties (k=2) of the "2/3 action levels" and "1/6 action levels" are in the range of $U(X_{pt}) = \pm 5-10 \%$.

Interpretation of 2/3 and 1/6 Action Level Detection

A positive detection of the 2/3 action level enables a reliable decision as to whether a measurement result is below the action level, even if the measurement uncertainty of the analytical method is about $\pm 50\%$.

The positive detection of the 1/6 action level can demonstrate the suitability of the applied method at lower values close to the LOQ or LOD.

Composition of Material

Ingredients	Amounts
Rice flour, organic	74 - 76 %
Maltodextrin	24 - 26 %
Allergen-Premixes Ingredients: Maltodextrin (74% - 95%), Sodium Chloride, Sodium Sulfate, Silicon dioxide and Allergens (5% - 25% each)	0,01 - 0,4 %

Added allergenic ingredients 2/3 and 1/6 values of the "action levels" are indicated as actually spiked total food item and calculated protein contents in mg/kg

Ingredients *	"Action Level"	Sample 1	Sample 2	Sample 3	Sample 4
Protein % (Kf = Kjeldahl factor)	Vital 4.0	[mg/kg]	[mg/kg]	[mg/kg]	[mg/kg]
Crustaceae: King prawns, raw, freeze-dried Protein 87,0% (Kf 6,25) (mixture, 1 product from aquaculture)	Protein 250 mg/kg	negative	1/6 Level Food 48,3 Protein 42,0	2/3 Level Food 189 Protein 164	negative
Egg: Whole egg powder, pasteurized, spray dried Protein 46,9% (Kf 6,25) (mixture (6 products from Europe)	Protein 20 mg/kg	2/3 Level Food 27,9 Protein 13,1	negative	negative	1/6 Level Food 7,09 Protein 3,33
Fish: Cod (<i>Gadus morhua</i>), raw, freeze-dried Protein 78,4% (Kf 5,6) (mixture, 2 products from North East Atlantic)	Protein 50 mg/kg	negative	2/3 Level Food 41,5 Protein 32,5	1/6 Level Food 10,0 Protein 7,87	negative
Milk: Skimmed milk powder Protein 33,0% (Kf 6,38) (mixture, 9 products from Europe and USA)	Protein 20 mg/kg	2/3 Level Food 39,7 Protein 13,1	negative	negative	1/6 Level Food 10,2 Protein 3,38
Molluscs: Yesso Scallop (<i>Mizuhopecten yessoensis</i>), raw, freeze dried Protein 75,7% (Kf 6,25) (mixture, 1 product from aquaculture, Japan)	Protein 200 mg/kg	2/3 Level Food 173 Protein 131	negative	negative	1/6 Level Food 43,9 Protein 33,2
Mustard, yellow: Mustard seed (<i>Sinapis alba</i>), milled Protein 30,7% (Kf 6,25) (mixture, 9 products from Asia and Europe)	Protein 10 mg/kg	negative	negative	negative	1/6 Level Food 5,84 Protein 1,79
Mustard, brown: Mustard seed (<i>Brassica juncea</i>), milled Protein 27,6% (Kf 6,25) (mixture, 1 product from Canada)	Protein 10 mg/kg	negative	2/3 Level Food 23,4 Protein 6,46	negative	negative
Mustard, black: Mustard seed (<i>Brassica nigra</i>), milled Protein 27,3% (Kf 6,25) (mixture, 1 product from Germany)	Protein 10 mg/kg	negative	negative	2/3 Level Food 23,9 Protein 6,53	negative
Soya: Soybeans, toasted, milled Protein 37,8% (Kf 5,71) (mixture, 6 products from Asia, Europe and USA)	Protein 100 mg/kg	1/6 Level Food 42,8 Protein 16,2	negative	negative	2/3 Level Food 175 Protein 66,2

* Allergen contents of „food item“ as indicated in the column of ingredients according gravimetric mixing

**Protein contents according to laboratory analysis (total nitrogen, Kjeldahl)

Note: The metrological traceability of temperature, mass and volume during production of the PT samples is ensured by DAkkS-compliant calibrated reference materials.

The detectability or absence of the allergens was tested by DLA using lateral flow assays. The results are in agreement with the spiking of the PT samples 1-4.

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).

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) (for more details see final report of PT).

Reference Values

All reference values were derived from the related proficiency test (PT) round (for more details see final report).

Reference Values qualitative (Consensus Values*)

Methods	Sample 1	Sample 2	Sample 3	Sample 4
Crustaceae		1/6 Level	2/3 Level	
Crustaceae ELISA / LFD	negative	positive	positive	negative
Crustaceae PCR / NGS	negative	positive	positive	negative
Egg	2/3 Level			1/6 Level
Egg ELISA / LFD	positive	negative	negative	positive
Fish		2/3 Level	1/6 Level	
Fish ELISA / LFD	negative	positive	positive	negative
Fish PCR / NGS	negative	positive	positive	negative
Milk	2/3 Level			1/6 Level
Milk ELISA / LFD	positive	negative	negative	positive
Molluscs	2/3 Level			1/6 Level
Molluscs ELISA / LFD	positive	positive**	positive**	positive
Molluscs PCR / NGS	positive	negative	negative	positive
Mustard		2/3 Level	2/3 Level	1/6 Level
Mustard ELISA / LFD	negative	positive	positive	positive
Mustard (in general) PCR / NGS	negative	positive	positive	positive
Mustard (brown and black, Brassica ssp) PCR / NGS	negative	none***	none***	none***
Mustard (yellow, Sinapis alba) PCR / NGS	negative	none***	none***	positive
Soya	1/6 Level			2/3 Level
Soya ELISA / LFD	positive	negative	negative	positive
Soya PCR / NGS	positive	negative	negative	positive

* Consensus values $\geq 75\%$ positive or negative results of PT-participants

** The participants obtained positive results for sample 2 and sample 3 which contain crustaceae (without addition of molluscs). Possible cross-reactivities should be documented in the manufacturer's test kit information

*** For marked samples inconsistent results were obtained, so that no consensus values could be obtained.

Note: Some unexpected positive results can be due to possible cross-reactivities of the applied methods (for more details see final report). Possible cross-reactivities should be documented in the manufacturer's test kit information.

Intended Use

- for laboratory use only, no food!
- validation of analytical methods
- control sample for quality control charts
- test material for inter-laboratory comparisons

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 30 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.



created	approved (PT-Coordinator)	updated
Matthias Besler-Scharf, PhD	Matthias Besler-Scharf, PhD	-
<i>signed M. Besler-Scharf</i>	<i>signed M. Besler-Scharf</i>	-
6 October 2026	6 October 2026	-