# PRODUCT INFORMATION SHEET

# *β-Lactoglobulin, Casein and Gluten in Infant Food (Infant Soy Formula)*

*PT originated REFERENCE MATERIAL (RM)*

**Description of the RM**

| | |
|---|---|
| Name / Material of related PT | *DLA ptAL03 (2023) Allergens III: β-Lactoglobulin, Casein and Gluten in Infant Food (Infant Soy Formula) - Sample A* |
| Identifier / LOT | *RM 2023-AL03 A* |
| Expiry date | *July 2027* |
| Matrix | *Infant Soy Formula* |
| Physical description | *Powder* |
| Packaging / weight | *Sealed foil pouche / 25 g* |
| Storage conditions | *cooled 2 - 10°C, long term frozen < -18°C (dry and dark)* |
| Name and address manufacturer | ***DLA - Proficiency Tests GmbH***<br>*Hauptstr. 80, 23845 Oering, Germany*<br>*Tel. ++49-(0)4532-9183358, Fax. ++49(0)4102-9944976*<br>*eMail. pt@dla-lvu.de, website. www.dla-lvu.de* |

**Composition of Material**

| Ingredients | Amounts |
|---|---|
| ***Infant Soy Formula, "dairy free"*** *(from birth)*<br>**(for dietary management in cow's milk allergy or intolerance)**<br>*Ingredients: maltodextrin, vegetable oils, soy protein isolate, vitamins, minerals, amino acids and other food additives*<br>*Nutrients per 100 g powder:*<br>*Fat 23 g, Carbohydrates 58 g, Protein 11 g, Salt 0,5 g* | 99,9 g/100 g |
| ***Milk component 1:***<br>**skimmed milk powder** mixture (9 products from Europe, USA)<br>– as skimmed milk powder*<br>– *thereof 33,0% total protein***<br>– *thereof casein****<br>– *thereof β-lactoglobulin**** | <br><br>52,8 mg/kg<br>17,4 mg/kg<br>13,9 mg/kg<br>1,74 mg/kg |
| ***Milk component 2:***<br>**whey powder** mixture (4 products from Germany)<br>– as whey powder*<br>– *thereof 15,9% total protein***<br>– *thereof β-lactoglobulin**** | <br><br>257 mg/kg<br>40,9 mg/kg<br>20,4 mg/kg |
| ***Sum of milk components***<br>– total protein<br>– casein<br>– total β-lactoglobulin | 310 mg/kg<br>58,3 mg/kg<br>13,9 mg/kg<br>22,1 mg/kg |
| ***Wheat:***<br>**wheat flour** mixture (21 products from Europe, Asia, USA)<br>– as wheat flour*<br>– *thereof 10,1% total protein***<br>– *thereof gluten**** | <br><br>200 mg/kg<br>20,2 mg/kg<br>17,4 mg/kg |
| *further Ingredients: Maltodextrin 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=6,38 for milk protein and F=5,7 for wheat protein)

*** Protein contents according to literature values (approx. 80% casein and 10% β-latcoglobulin in total milk protein; approx. 50% β-Lactoglobulin in whey protein; 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 1 - 5 g.
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 ≤ 25% („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** | **β-Lactoglobulin** | |
|---|---|---|
| | Method RS-F* | Other Methods* |
| Number of results | *5* | *6°* |
| Number of outliers | *0* | *2* |
| ***Assigned Value (Xpt)*** | ***10,7*** | ***4,32*** |
| Robust standard deviation | *1,45* | *2,78* |
| Standard uncertainty | *0,813* | *1,42* |
| Target standard deviation σpt | *2,68* | *1,08* |
| ***Target range*** | ***5,35 – 16,1*** | ***2,16 – 6,48*** |

* ELISA Method: Ridascreen® Fast, R-Biopharm and “other methods”: all except RS-F
° without outliers

| **Parameter** | **Casein** | | |
|---|---|---|---|
| | All Results* | Method RS-F** | Other Methods*** |
| Number of results | *18* | *7* | *11* |
| Number of outliers | *0* | *0* | *0* |
| ***Assigned Value (Xpt)*** | ***7,86*** | ***5,08*** | ***9,69*** |
| Robust standard deviation | *4,80* | *3,50* | *4,80* |
| Standard uncertainty | *1,41* | *1,65* | *1,81* |
| Target standard deviation σpt | *1,97* | *1,27* | *2,42* |
| ***Target range*** | ***3,93 – 11,8*** | ***2,54 – 7,62*** | ***4,84 – 14,5*** |

* Results of diverse ELISA Methods
** ELISA Method: Ridascreen® Fast, R-Biopharm
*** Results of other ELISA methods: all except RS-F (Ridascreen® Fast, R-Biopharm)

| **Parameter** | **Gluten** | |
|---|---|---|
| | All Results* | Method RS** |
| Number of results | *27* | *16* |
| Number of outliers | *0* | *0* |
| ***Assigned Value (Xpt)*** | ***26,5*** | ***24,6*** |
| Robust standard deviation | *7,25* | *4,06* |
| Standard uncertainty | *1,74* | *1,27* |
| Target standard deviation σpt | *6,63* | *6,16* |
| ***Target range*** | ***13,3 – 39,8*** | ***12,3 – 37,0*** |

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

**Reference Values qualitative ELISA**

| Parameter | β-Lactoglobulin* | Casein* | Milk (as total Milk proteins)* | Gluten* |
|---|---|---|---|---|
| Number positive | 15 | 19 | 9 | 28 |
| Number negative | 0 | 0 | 0 | 0 |
| Percent positive | 100 | 100 | 100 | 100 |
| Percent negative | 0 | 0 | 0 | 0 |
| ***Consensus value*** | ***positive*** | ***positive*** | ***positive*** | ***positive*** |

* Results of diverse ELISA Methods (LODs 0,0015-1,5 mg/kg β-Lactoglobulin, 0,04-2,5 mg/kg casein, 0,05-2,5 mg/kg milk proteins and 0,3-10 mg/kg gluten)

**Reference Values qualitative PCR**

| Parameter | Wheat |
|---|---|
| Number positive | 2 |
| Number negative | 0 |
| Percent positive | 100 |
| Percent negative | 0 |
| ***Consensus value*** | ***positive*** |

* Results of diverse PCR Methods (LODs positive results not indicated)

**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 29 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:** 15 May 2024

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

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