

Reference Material MOSH/MOAH in infant formula

P2402-RMIf



- Summary -

Please note:

Reference material P2402-RMIf is validated in method ring test P2402-MRT, which is organised, performed, and evaluated according to the requirements of DIN EN ISO/IEC 17043 and the “International Harmonized Protocol”. DIN ISO 13528 is considered during the evaluation of the submitted results of P2402-MRT and during homogeneity testing. Details related to the applied statistics are summarised in the full specification, which is provided after purchase of the reference material.

Reference material P2402-RMIf consists of 75 g of infant formula (powder), which is spiked with a technical white oil and a lubricant (see table 1).

The corresponding unspiked infant formula (powder) is available as blank material P2402-BLIf (50 g). The blank material contains about 2.1 mg/kg of total MOSH, while it is free from total MOAH < 0.5 mg/kg (see table 2).

10 laboratories took part in method ring test P2402-MRT. The spiked levels as well as the assigned values, which are calculated of the results of the participants of P2402-MRT, are summarised in table 1.

Table 1. Reference material P2402-RMIf - spiked levels and assigned values

Parameter	Spiked level [mg/kg]	Assigned value [mg/kg]	Total number of results
Total MOSH (total hump) (\geq n-C10 to \leq n-C50)	4.2*	7.95	9
Total MOAH (total hump) (\geq n-C10 to \leq n-C50)	3.8	3.82	9

* The spiked level of total MOSH is provided for information only. The blank material contains 2.1 mg/kg of total MOSH and it is assumed that the test material was contaminated with MOSH during the advanced preparation process of the test material (solving, spiking, freeze-drying, milling, homogenising).

Table 2. Blank material P2402-BLIf - assigned values

Parameter	Spiked level [mg/kg]	Assigned value [mg/kg]	Total number of results
Total MOSH (total hump) (\geq n-C10 to \leq n-C50)	unspiked	2.13	9
Total MOAH (total hump) (\geq n-C10 to \leq n-C50)	unspiked	< 0.5	9

In P2402-MRT, the labs were instructed to determine total MOSH and total MOAH in accordance with the guidance document of the Joint Research Centre of the European Commission (5) as follows:

“[...]by integrating the chromatogram,

- from the retention time of the beginning of the n-C10 peak;*
- to the retention time of the end of the n-C50 peak;*
- after the trimming of the riding peaks [...] above the hump(s); and*
- after the subtraction of/adjustment for the reagent blank (baseline).*

The obtained “corrected hump” should be an unambiguously identified smooth hump“ (page 15).