

JOINT RESEARCH CENTRE
Directorate F – Health and Food

REFERENCE MATERIAL CERTIFICATE

ERM[®] - BD087 INFANT FORMULA

Certified Values		
	Mass Fraction ⁶⁾ [µg/kg]	Uncertainty ⁷⁾ [µg/kg]
3-MCPD fatty acid esters ^{1,2)}	70	10
2-MCPD fatty acid esters ^{1,3)}	30	5
Sum of 3-MCPD and 3-MCPD fatty acid esters ^{1,4)}	70	10
Sum of 2-MCPD and 2-MCPD fatty acid esters ^{1,5)}	30	5
1) As obtained by GC-MS and GC-MS/MS after hydrolysis. 2) 3-monochloropropanediol fatty acid esters, expressed as 3-MCPD [CAS 96-24-2]. 3) 2-monochloropropanediol fatty acid esters, expressed as 2-MCPD [CAS 497-04-1]. 4) Sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD. 5) Sum of 2-monochloropropanediol (2-MCPD) and 2-MCPD fatty acid esters, expressed as 2-MCPD. 6) Certified values are values that fulfil the highest standards of accuracy. The given values represent the unweighted mean value of the means of accepted sets of data, each set being obtained in a different laboratory and/or with a different method of determination. The certified value and its uncertainty are traceable to the International System of Units (SI). 7) The uncertainty of the certified value is the expanded uncertainty with a coverage factor $k = 2$ corresponding to a level of confidence of about 95 % estimated in accordance with ISO 17034:2016 and ISO Guide 35:2017.		

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used is 0.4 g.

Geel, November 2023

INFORMATION ONLY

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2440 Geel, Belgium

Additional Material Information	
	Value ³⁾
Fat content	25.7 %
3-MCPD ¹⁾	< 5 µg/kg
2-MCPD ²⁾	< 5 µg/kg
1) 3-monochloropropanediol [CAS 96-24-2] 2) 2-monochloropropanediol [CAS 497-04-1] 3) These values refer to values that were obtained in the course of the study. They are usually derived from single measurements only, are stated without an uncertainty and give merely information about material properties that may be of interest for the user.	

DESCRIPTION OF THE MATERIAL

ERM-BD087 is an infant formula containing fatty acid esters of 3-MCPD and 2-MCPD. The material is available in glass bottles containing at least 30 g of spray-dried infant formula powder, sealed under an atmosphere of nitrogen.

ANALYTICAL METHODS USED FOR CHARACTERISATION

GC-MS and GC-MS/MS after hydrolysis.

PARTICIPANTS

The following laboratories performed measurements in the scope of the homogeneity, stability and/or characterisation study.

Agència de Salut Pública de Barcelona, Barcelona, ES
(measurements under the scope of ISO/IEC 17025:2017 accreditation ENAC No. 227/LE459, 227/LE1338)

AGROLAB Dr, Verwey B.V., Barendrecht, NL
(measurements under the scope of ISO/IEC 17025:2017 accreditation RvA No. L234)

Danmarks Tekniske Universitet Fødevareinstituttet, Kgs. Lyngby, DK
(measurements under the scope of ISO/IEC 17025:2017 accreditation DANAK No. 350)

Dublin Public Analyst's Laboratory, Dublin, IE
(measurements under the scope of ISO/IEC 17025:2017 accreditation INAB No. 99T)

EUROFINS Lab Zeeuws Vlaanderen (LZV) B.V., Graauw, NL
(measurements under the scope of ISO/IEC 17025:2017 accreditation RvA No. L201)

EUROFINS WEJ Contaminants GmbH, Hamburg, DE
(measurements under the scope of ISO/IEC 17025:2017 accreditation DAkkS No. D-PL-14602-01-00)

I.A.P.R General Chemical State Laboratory, Athens, GR

Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH, Linz, AT
(measurements under the scope of ISO/IEC 17025:2017 accreditation AA No. 0452)

Prüfinstitut Chemische Analytik GmbH, Berlin, DE

Service Commun des Laboratoires, Massy, FR
(measurements under the scope of ISO/IEC 17025:2017 accreditation Cofrac No. 1-0162)

SGS Germany GmbH, Hamburg, DE
(measurements under the scope of ISO/IEC 17025:2017 accreditation DAkkS No. D-PL-11020-04-01)

TLR International Laboratories BV, Ridderkerk, NL

SAFETY INFORMATION

The usual laboratory safety precautions apply.

INTENDED USE

The material is intended for the quality control assessment of method performance.

INSTRUCTIONS FOR USE

The material must be re-homogenised by repeatedly turning over the unit and shaking it for 2 min.

The determination of MCPD fatty acid esters is performed in the extractable fat fraction of infant formula, as these compounds are lipophilic. However, milk-based infant formula ingredients commonly have protein-linked fat, which is not easily extractable. Moreover, some infant formulae contain microencapsulated fat contingents, which are not easily accessible neither. Thus, the analysis of MCPD fatty acid esters in infant formula powder matrix combined with the low maximum levels for these compounds poses some analytical challenges. There are some indications that the presence of water may aid to overcome the extraction challenges, although the mechanism is not completely known. It should therefore be considered whether the addition of water to the CRM prior or during the extraction step is beneficial. During the characterisation study, various validated extraction principles were used with or without addition of water, and demonstrated acceptable results.

Dispose in accordance with good laboratory practice.

For general information on handling of reference materials, please see ERM Application Note 6, available on <https://crm.jrc.ec.europa.eu/e/132/User-support-Application-Notes>.

STORAGE

The material should be stored at $(-20 \pm 5) ^\circ\text{C}$.

For more information regarding the shelf life of reference materials please see ERM Application Note 7, available on <https://crm.jrc.ec.europa.eu/e/132/User-support-Application-Notes>.

The unit can be reopened and used for up to 7 days after opening, if the unit is properly closed. Further than this period of time has not been tested and occurs under the responsibility of the user.

The European Commission cannot be held responsible for changes that happen to samples after opening or when the material is stored differently from the stated storage conditions at the customer's premises.

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NOTE

A detailed certification report is available at <https://crm.jrc.ec.europa.eu/>.



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