

Changes to legislation: Commission Regulation (EC) No 1609/2006, ANNEX is up to date with all changes known to be in force on or before 05 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

ANNEX

Specifications for the protein source, protein processing and protein quality used in the manufacture of infant formula based on hydrolysates of whey protein derived from cows' milk protein

(1) Protein content

Protein content = nitrogen content \times 6,25

Minimum	Maximum
0,44 g/100 kJ	0,7 g/100 kJ
(1,86 g/100 kcal)	(3 g/100 kcal)

(2) Protein source

Demineralised sweet whey protein derived from cows' milk after enzymatic precipitation of caseins using chymosin, consisting of:

- (a) 63 % caseino-glycomacropeptide free whey protein isolate with a minimum protein content of 95 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3 %; and
- (b) 37 % sweet whey protein concentrate with a minimum protein content of 87 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3,5 %.

(3) Protein processing

Two-stage hydrolysis process using a trypsin preparation with a heat treatment step (from 3 to 10 minutes at 80 to 100 °C) between the two hydrolysis steps.

(4) Protein quality

Essential and semi-essential amino acids in breast milk as set out in Annex V to Directive 91/321/EEC.

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Changes and effects yet to be applied to :

- Regulation repeal by [EUDR 2006/141](#) Directive