

*No. 1 choice
of hospitals
& mothers*

CFU limitations for Medela Ready-to-Use products

The production and packaging process as well as the microbiological checks that are carried out before the release of each product LOT guarantee, that there are only a safely low number of nonpathogenic germs, and overall, no pathogenic germs on the products.

The applicable CFU (colony-forming unit) limitation levels for Medela Ready-to-Use products have been derived from the German legislation for the quality of water intended for human consumption ¹. They are continuously monitored per production LOT in accordance with EN ISO 11737-1 ². In practice, the bioburden of each LOT of products is tested against the limitation level (CFU/product) by means of sample testing before release for sale. The achieved average level of CFUs per product during the year 2014 and the limitation level for each product are shown in Table 1.



Article number	Article name	Limitation level (CFU/product) ³	Achieved average level (CFU/product) ⁴
200.2957	Ready-to-Use Single-Use Bottle 80 mL	30	0
200.2956	Ready-to-Use Single-Use Bottle 150 mL	55	0
200.4802	Ready-to-Use Single-Use Bottle 250 mL	90	0
008.0257	Ready-to-Use Calmita Starter	10	0,2
008.0258	Ready-to-Use Calmita Advanced	10	0,2
008.0276	Ready-to-Use One-Day Symphony Pump Set size M	24	0,2
008.0277	Ready-to-Use One-Day Symphony Pump Set size L	24	0,1
008.0278	Ready-to-Use One-Day Symphony Pump Set size XL	24	0,3
008.0269	Ready-to-Use One-Day Lactina Pump Set size M	24	0,0
008.0270	Ready-to-Use One-Day Lactina Pump Set size L	24	0,4
008.0271	Ready-to-Use One-Day Lactina Pump Set size XL	24	0,0

Table 1: CFU limitation level and achieved average CFU level

Moreover, microbiological checks that are carried out before the release of each product LOT guarantee that there are no pathogenic bacteria on the products (Table 2). In accordance with the German Consulting Centre for Hospital Epidemiology and Infection Control (Deutsches Beratungszentrum für Hygiene) the following bacteria are considered as pathogenic for term and preterm born infants (Table 3) ⁵.

Article number	Article name	Limitation level for pathogenic bacteria (CFU) ²
200.2957	Ready-to-Use Single-Use Bottle 80 mL	0 per 10 bottles
200.2956	Ready-to-Use Single-Use Bottle 150 mL	0 per 10 bottles
200.4802	Ready-to-Use Single-Use Bottle 250 mL	0 per 10 bottles
008.0257	Ready-to-Use Calmita Starter	0 per 10 teats
008.0258	Ready-to-Use Calmita Advanced	0 per 10 teats
008.0276	Ready-to-Use One-Day Symphony Pump Set size M	0 per 10 pump sets
008.0277	Ready-to-Use One-Day Symphony Pump Set size L	0 per 10 pump sets
008.0278	Ready-to-Use One-Day Symphony Pump Set size XL	0 per 10 pump sets
008.0269	Ready-to-Use One-Day Lactina Pump Set size M	0 per 10 pump sets
008.0270	Ready-to-Use One-Day Lactina Pump Set size L	0 per 10 pump sets
008.0271	Ready-to-Use One-Day Lactina Pump Set size XL	0 per 10 pump sets

Table 2: Limitation level for pathogenic bacteria for Ready-to-Use products

Pathogenic bacteria

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| <i>Escherichia coli</i> | <i>Streptococcus pneumoniae</i> |
| <i>Enterococcus</i> spp. | <i>Streptococcus pyogenes</i> (A-Streptococci) |
| <i>Pseudomonas aeruginosa</i> | <i>Staphylococcus aureus</i> |
| <i>Shigella</i> spp. | Coagulase-negative <i>Staphylococcus</i> spp. |
| <i>Salmonella</i> spp. | <i>Corynebacterium diphtheriae</i> |
| <i>Yersinia</i> spp. | <i>Clostridium botulinum</i> |
| <i>Bacillus cereus</i> | <i>Clostridium difficile</i> |
| <i>Streptococcus agalactiae</i> (B-Streptococci) | |

Table 3: Non-permissible pathogenic bacteria defined by the German Consulting Centre for Hospital Epidemiology and Infection Control (Deutsches Beratungszentrum für Hygiene)⁵.

References

- 1 Federal Ministry of Justice. German legislation for the quality of water intended for human consumption (Trinkwasserverordnung – TrinkwV 2001) (2001).
- 2 EN ISO 11737-1: Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of micro-organisms on products.
- 3 Medela. CFU limitations for Medela Ready-to-Use products based on Federal Ministry of Justice. German legislation for the quality of water intended for human consumption (Trinkwasserverordnung – TrinkwV 2001) (2001).
- 4 Medela. CFU limitations for Medela Ready-to-Use products (Monitoring Data 2014/2017).
- 5 German Consulting Centre for Hospital Epidemiology and Infection Control (Deutsches Beratungszentrum für Hygiene). Conclusion of the Risk Assessment of the Production Method for Ready-to-Use Products (2014).

Products may not be available in all countries. For further information about Medela products, visit www.medela.com and look for location finders in your country or contact your local Medela representative.

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