

# Existing Authorisations

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## Existing Authorisations

12. Calcium tert-butylphosphonate is approved as a Food Contact Substance (FCS) in the USA under Food Contact Notification (FCN) No 2211 with effect from 8th April 2022, for use as a nucleating agent in the manufacture of polyolefin food contact materials and articles, including for use in contact with infant formula and human milk. The substance is subject to the following limitations/specifications: The FCS will be used at a maximum level of 0.15 weight percent in polyolefins in contact with all food types under Conditions of Use A through H and J (microwave only, excluding susceptor applications (i.e. where the microwave energy is converted to thermal energy)). The FCS may be used in articles intended to contact infant formula and human milk.

13. In March 2024, the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) concluded that “calcium tert-butylphosphonate does not raise a safety concern for the consumer if used as a nucleating agent up to 0.15% w/w in the manufacture of polyolefin FCM that are intended to be in contact with all types of food for storage above 6 months at room temperature and below, including temperatures up to 100°C for maximum 2h and up to 130°C for short durations.” However, the EFSA Panel was unable to evaluate the safety

of its use for manufacture of FCMs for contact with infant formula and human milk (EFSA, 2024).