Committee Advice Document on Calcium tert-butylphosphonate as an additive for use in the manufacture of plastic food contact materials and articles

Summary and Introduction

In this guide

In this guide

Summary

1. Calcium tert-butylphosphonate will be used at a maximum level of 0.15 weight per cent (wt %) in polyolefins in contact with all food types. In line with assimilated Regulations No 10/2011 and No 1935/2004, the assessment has considered aspects of the plastic additive, such as physical and chemical properties, migration data and toxicological data and its conditions of use, which have formed the basis and structure for the assessment.

2. The information on the identity of the substance, the physical and chemical properties and intended application were considered satisfactory.

3. Results from the overall and specific migration tests demonstrated the migration of calcium tert-butylphosphonate to be close to or below the limit of detection (up to 10 µg/kg).

4. Owing to the low migration of calcium tert-butylphosphonate as an additive under the conditions of use specified in the application, limited toxicology testing was required.

5. Calcium tert-butylphosphonate was negative in the in vitro Ames test and in vitro micronucleus (MN) assay and therefore unlikely to be of concern for genotoxicity, especially given its low exposure in humans.

6. Overall, there is unlikely to be a risk to health from the use of calcium tert-butylphosphonate as an additive in the manufacture of plastic materials and articles intended to be in food contact with food.

7. Calcium tert-butylphosphonate was therefore recommended for approval for use as an additive as outlined in the application and specified above.

8. However, a potential health risk to infants <16 weeks via feeding bottles could not be assessed because infants <16 weeks are expected to be exclusively fed on breast milk and/or bottle fed on infant formula. There is a lack of data for these circumstances with regard to the sensitivity of this age group.

Introduction

9. The Applicant, submitted an application to the Food Standards Agency (FSA) regarding the use of calcium tert-butylphosphonate as a nucleating agent in the manufacture of polyolefin (polypropylene and polyethylene) Food contact Materials (FCMs) and articles, including for use in contact with infant formula and human milk.

10. The utilisation of the additive as a nucleating agent in the manufacture of polyolefin materials brings a number of claimed advantages. The benefits described by the Applicant for polypropylene materials included reduced processing cycle time of injection moulded parts, increased stiffness and reduced hazing. For polyethylene materials, including rigid and film articles, the benefits described by the Applicant included reduced hazing, highly modified shrinkage properties, increased gloss and/or clarity, and/or reduction of water vapour and oxygen permeation rates.

11. The Food Contact Materials Joint Expert Group (FCMJEG) was requested to evaluate the information provided by the Applicant and provide a scientific opinion on the safety of calcium tert-butylphosphonate as an additive for use in the manufacture of plastic FCMs and articles.