

Conclusions of the FCMJEG

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Conclusions of the FCMJEG

112. Satisfactory information regarding the identity of the substance, its physical and chemical properties, the intended application of the substance, data on migration of the substance and toxicological data were submitted.

113. Results from the overall and specific migration test demonstrated that the migration of calcium tert-butylphosphonate was close to or below the limit of detection (up to 10 µg/kg).

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

115. Overall, there is unlikely to be a genotoxicity 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.

116. A potential health risk to infants (<16 weeks old) via feeding bottles, based on neurotoxic effects could not be assessed due to lack of available data for this age group.

117. Overall, the FCMJEG considered the information and data provided was sufficient to conclude that there was no concern for the general population from the use of calcium tert-butylphosphonate as an additive for use in food contact materials and articles. Use in contact with infant formula and human milk was excluded due to the lack of neurotoxicity data and the potentially sensitive nature of the infant group (<16 weeks).

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

Abbreviations

Abbreviation	Definition
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ATR-IR	Attenuated total reflection infrared
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CoA	Certificate of analysis
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CytB	Cytochalasin B
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DMSO	Dimethyl sulfoxide
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DMF	Dimethylformamide
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EFSA	European Food Standards Agency
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FCM	Food contact material
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FCMJEG	Food Contact Materials Joint Expert Group
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FCN	Food contact notification
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FCS	Food contact substance
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FSA	Food Standards Agency
GC	Gas chromatography
GLP	Good laboratory practice
HDPE	High-density polyethylene
LC-MS	Liquid chromatography-mass spectrometry
LDPE	Low-density polyethylene
LLDPE	Linear low-density polyethylene
LOD	Limit of detection
MN	Micronucleus
NIAS	Non-intentionally added substance
NMR	Nuclear magnetic resonance
PP	Polypropylene
SIR	Selected ion recording
TGA	Thermogravimetric analysis

Glossary

Susceptor A piece of metallic film on a package of microwaveable food that helps cook and brown the food by producing and concentrating energy on the food's outer surface (Dictionary, 2024)

Nucleating agent Nucleating agents are inorganic materials added to polymers to increase the crystallinity and shorten the cycle times. They speed up the transition from melted to solid material. Changing the crystallinity of plastics changes properties like density and clarity (Special Chem, 2024).

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