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SCIENTIFIC OPINION

Re-evaluation of shellac (E 904) as a food additive and a new application on the extension of use of shellac (E 904) in dietary foods for special medical purposes

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Abstract

The present opinion deals with the re-evaluation of shellac (E 904) when used as a food additive and with the new application on the extension of use of shellac (E 904) in dietary foods for special medical purposes. The Panel derived an acceptable daily intake (ADI) of 4 mg/kg body weight (bw) per day for wax-free shellac (E 904) produced by physical decolouring, based on a NOAEL of 400 mg/kg bw per day and applying an uncertainty factor of 100. The Panel concluded that the ADI of 4 mg/kg bw per day should be considered temporary for wax-free shellac (E 904) produced by chemical bleaching, while new data are generated on the identity and levels of the organochlorine impurities in E 904. This ADI is not applicable for wax-containing shellac as a food additive. For several age groups, the ADI was exceeded at the 95th percentile in the non-brand-loyal exposure assessment scenario and maximum level exposure assessment scenario. Considering the low exceedance and the fact that both the exposure estimation and the toxicological evaluation of shellac were conservative, the panel concluded that the calculated exceedance of the ADI does not indicate a safety concern. The Panel recommended to the European Commission separating specifications for E 904 depending on the manufacturing process, chemical bleaching and physical decolouring, because they result in different impurities; revising the definition of the food additive to include a description of each manufacturing process; deleting information on wax-containing shellac from the EU specifications; revising the acid value for wax-free shellac produced by chemical bleaching; lowering the maximum limit for lead; to consider introducing limits for other toxic elements potentially present in shellac; including a maximum limit for chloroform and total inorganic chloride in the EU specification for shellac produced by chemical bleaching.

KEYWORDS

chemical bleaching, E 904, extension of use, food additive, physical decolouring, shellac

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