

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

EFSA Panel on Food Additives and Flavourings (FAF) | Maged Younes | Gabriele Aquilina | Laurence Castle | Gisela Degen | Karl-Heinz Engel | Paul Fowler | Maria Jose Frutos Fernandez | Peter Fürst | Rainer Gürtler | Ursula Gundert-Remy | Trine Husøy | Melania Manco | Wim Mennes | Peter Moldeus | Sabina Passamonti | Romina Shah | Ine Waalkens-Berendsen | Matthew Wright | Polly Boon | Riccardo Crebelli | Alessandro Di Domenico | Alicja Mortensen | Ruud Woutersen | H. Henk Van Loveren | Gabriele Gagliardi | Elena Mazzoli | Federica Lodi | Josef Daniel Rasinger | Ana Maria Rincon | Alexandra Tard | M. J. Frutos Fernandez

Correspondence: fip@efsa.europa.eu

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.

KEY WORDS

chemical bleaching, E904, extension of use, food additive, physical decolouring, shellac

This is an open access article under the terms of the [Creative Commons Attribution-NoDerivs](https://creativecommons.org/licenses/by-nd/4.0/) License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

© 2024 European Food Safety Authority. *EFSA Journal* published by Wiley-VCH GmbH on behalf of European Food Safety Authority.

CONTENTS

Abstract.....	1
Summary.....	4
1. Introduction.....	6
1.1. Background and Terms of Reference as provided by the requestor.....	6
1.1.1. Background.....	6
1.1.1.1. Re-evaluation of shellac (E 904) as a food additive under Regulation (EU) No 257/2010.....	6
1.1.1.2. Application of shellac (E 904) for an extension of use in foods for special medical purposes in tablet and coated tablet form.....	6
1.1.2. Terms of Reference.....	7
1.1.2.1. Re-evaluation of shellac (E 904) as a food additive under Regulation (EU) No 257/2010.....	7
1.1.2.2. Application of shellac (E 904) for an extension of use in foods for special medical purposes in tablet and coated tablet form.....	7
1.2. Information on existing evaluations.....	7
2. Data and methodologies.....	8
2.1. Data.....	8
2.2. Methodologies.....	8
3. Assessment.....	8
3.1. Technical data.....	8
3.1.1. Identity of the food additive and specifications.....	8
3.1.2. Manufacturing process.....	12
3.1.3. Methods of analysis in food.....	12
3.1.4. Stability of the substance and reaction and fate in food.....	13
3.2. Authorised uses and use levels.....	14
3.3. Exposure data.....	14
3.3.1. Reported use levels of shellac (E 904).....	14
3.3.2. Summarised data extracted from the Mintel's global new products database.....	15
3.3.3. Food consumption data used for exposure assessment.....	15
3.4. Exposure estimates.....	17
3.4.1. Exposure to shellac (E 904) from its use as a food additive.....	17
3.4.2. Proposed extension of use of shellac (E 904).....	19
3.5. Assessment of the specifications for shellac (E 904).....	20
3.6. Biological and toxicological data.....	21
3.6.1. Absorption, distribution, metabolism and excretion.....	22
3.6.2. Acute toxicity.....	22
3.6.3. Short-term and subchronic toxicity.....	22
3.6.4. Genotoxicity.....	23
3.6.5. Chronic toxicity and carcinogenicity.....	26
3.6.6. Reproductive and developmental toxicity.....	27
3.6.7. Hypersensitivity.....	29
3.7. Discussion.....	29
4. Conclusions.....	32
5. Recommendations.....	32
6. Documentation as provided to EFSA.....	33
Abbreviations.....	35
Acknowledgements.....	36
Conflict of interest.....	36
Requestor.....	36

Question numbers.....	36
Copyright for non-EFSA content.....	36
Panel members.....	36
Map disclaimer.....	36
References.....	36
Appendix A.....	39
Appendix B.....	41
Annexes.....	42