

APPLICATION INFORMATION

12. TYPE OF SUBMISSION (Check One)

New Additive Petition Amendment* Supplement * Other

13. REASON FOR SUBMISSION

14. NUMBER OF VOLUMES SUBMITTED

15. THIS SUBMISSION IS (Check One)

Paper Paper and Electronic Electronic

THIS APPLICATION CONTAINS THE FOLLOWING ITEMS: (Check all that apply)

16 **Cover Letter*****

Petition Table of Contents (TOC)

Executive Summary

21 CFR 71.1 (C)

17 • **SECTION A – C: Chemistry Section**

- Chemistry Table of Contents (TOC)
- Identity Use Intended Technical Effect Analytical and Methodology
- Studies
- References

18 • **SECTION D: Safety Section****

- Safety of TOC
- Safety Summary
- Studies
 - Genetic Toxicity Studies
 - Acute Toxicity Studies
 - Short Term Toxicity Studies Between 14 Days and 28 Days
 - Subchronic Toxicity Studies 90 Days
 - Chronic Toxicity Studies Between 6 Months and 2 Year
 - Carcinogenicity Studies
 - Carcinogenicity Studies with in Utero Exposure
 - Combined Chronic Toxicity and Carcinogenicity Studies
 - Reproductive Toxicity Studies
 - Reproductive Toxicity with Teratology Phase
 - Teratology Studies
 - Immunotoxicity Studies
 - Allergenicity Studies
 - Metabolism and Pharmacokinetic Studies
 - Neurotoxicity Studies
 - Neurobehavioral Toxicity Studies
 - Epidemiology Studies
 - Human Clinical Studies
 - Nutrition Studies
 - Other Studies, e.g., Microbiology _____
- References

19 • **SECTION E - I: Administrative Section***

- Administrative TOC Probable Exposure Information Batch Certification Exemption
- Required Fee (*See box 10 of page 1*) Proposed Tolerance Proposed Regulation

20 • **SECTION J: Environmental Section**

- Environmental TOC
- Environmental Assessment Categorical Exclusion
- Studies
- References

21. SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT

22. TYPED NAME AND TITLE

23. DATE

* The cover letter for Supplement or Amendment should be placed in Administrative folder, e.g., Administrative->Correspondences->Incoming->Supplement Cover Letter.pdf.

** All of the categories in Safety Section should be placed inside of Studies folder in Safety Folder.

*** Original Submission only.

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Food and Drug Administration
CFSAN (HFS-265)
5100 Paint Branch Parkway
College Park, MD 20740

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