



**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.

**Public reporting burden for this collection of information** is estimated to average one hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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

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