

Department of Health and Human Services Food and Drug Administration FOOD ADDITIVE PETITION (FAP) COLOR ADDITIVE PETITION (CAP) FOOD MASTER FILE (FMF) COLOR MASTER FILE (CMF)	Form Approved: OMB No. 0910-0016; Expiration Date: xx/xx/xxxx (See last page for OMB Statement)
	FDA USE ONLY
	SUBMISSION NUMBER
	DATE OF RECEIPT

Transmit completed form and attachments electronically via the Electronic Submission Gateway (see Instructions); OR Transmit completed form and attachments in paper format or on physical media to: Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740-3835.

PART I - INTRODUCTORY INFORMATION ABOUT THE SUBMISSION

1. Type of Submission (*Complete a. or b. below*)

a. If New Submission, check one of the following.

☐ New Food Additive Petition (21 CFR 171.1)
 ☐ New Color Additive Petition (21 CFR 71.1)

☐ New Food Master File
 ☐ New Color Master File

b. If Additional Information/Incoming Correspondence, check one of the following.

☐ Update
 ☐ Amendment

Enter the appropriate number applicable to this update or amendment.

FAP Number
 FMF Number

CAP Number
 CMF Number

2. ☐ All electronic files included in this submission have been checked and found to be virus free. (*Check box to verify*)

3a. For New Submissions Only: Enter the date of most recent presubmission consultation (if any) with FDA on the subject substance (yyyy/mm/dd):

3b. For Amendments only: Is your amendment submitted in response to a communication from FDA? (*Check one*)

☐ Yes
 ☐ No
 If yes, enter the date of communication (yyyy/mm/dd):

PART II - INFORMATION ABOUT THE PETITIONER OR PERSON RESPONSIBLE FOR MASTER FILE

1a. Petitioner or Person Responsible for Master File	Name of Contact Person		Position	
	Company (<i>if applicable</i>)			
	Mailing Address (<i>number and street</i>)			
City		State or Province		Zip Code/Postal Code
Country				
Telephone Number		Fax Number		E-Mail Address
1b. Agent or Attorney (<i>if applicable</i>)	Name of Contact Person		Position	
	Company (<i>if applicable</i>)			
	Mailing Address (<i>number and street</i>)			
City		State or Province		Zip Code/Postal Code
Country				
Telephone Number		Fax Number		E-Mail Address

PART III - GENERAL ADMINISTRATIVE INFORMATION

1. Title of Submission _____

2. Submission Format (*Check appropriate box(es)*)☐ Electronic Submission Gateway☐ Paper☐ Electronic files on physical media with paper signature page

If applicable, give number and type of physical media _____

3. For paper submissions only

Number of volumes: _____

Total number of pages: _____

4. Does this submission incorporate any information in FDA's files by reference? (*Check one*)☐ Yes (*Proceed to item 5*)☐ No (*Proceed to item 6*)5. The submission incorporates by reference information from a previous submission to FDA as indicated below. (*Check all that apply*)☐ a) Food Additive Petition No. FAP _____☐ b) Food Master File No. FMF _____☐ c) Color Additive Petition No. CAP _____☐ d) Color Master File No. CMF _____☐ e) GRAS Notice No. GRN _____☐ f) GRAS Affirmation Petition No. GRP _____☐ g) Other or additional information (briefly describe or enter information in a format similar to a) through f)) _____6. Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information? (*Check one*)☐ Yes, see attached designation of confidential information☐ Yes, information is designated at the place where it occurs in the submission☐ No7. Have you attached a redacted copy of some or all of the submission? (*Check one*)☐ Yes, redacted copy of complete submission☐ Yes, redacted copy of part(s) of submission☐ No**PART IV.A - FOOD ADDITIVE PETITION ONLY**1. Additive Type (*Check one*)☐ Direct☐ Secondary Direct☐ Indirect☐ Source of Radiation2. Does the intended use of the additive include any use in meat, meat food product, or poultry product? (*Check one*)☐ Yes☐ No

The undersigned submits the attached petition pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act with respect to (state the name of the food additive and its proposed use) _____

PART IV.B - COLOR ADDITIVE PETITION ONLY1. Regulated products that would contain additive (*Check applicable*)☐ Food (including meat, meat food product or poultry product)☐ Food (excluding meat, meat food product or poultry product)☐ Food-contact material☐ Cosmetics ☐ Drugs ☐ Medical devices2. Fee enclosed (*Check one*)☐ New listing for color additive for use in food (\$3,000)☐ New listing for color additive for use in cosmetics, drugs, or medical devices (\$2,600)☐ Amendment for color additive for use in food (\$1,800)☐ Amendment for color additive for use in cosmetics, drugs, or medical devices (\$1,600)

The petitioner submits the attached petition pursuant to section 721(b)(1) of the Federal Food, Drug, and Cosmetic Act

requesting listing by the Commissioner of the color additive _____

as suitable and safe for use in or on _____

subject to the conditions that _____

PART IV.C - FOOD MASTER FILE OR COLOR MASTER FILE ONLY

1. Reason for the submission

2. When applicable, other information not addressed or listed on this form

PART V - IDENTITY
(Including all constituents)**Note:** When entering information in the table below, abbreviate Primary as P, and Constituents as C. (Include residual monomers, residual solvents, impurities (including carcinogenic impurities), catalysts, etc.)

Chemical Type	CAS* Registry Number	Chemical Name	Link To Chemical Structure	Trade Name (If any)

* CAS = Chemical Abstracts Service

Add Continuation Page

PART VI - OTHER ELEMENTS IN YOUR SUBMISSION
(check the list below to help ensure your submission is complete. check all that apply.)

1. ☐ Administrative

- 1.1 ☐ Designation of Nondisclosable Information
- 1.2 ☐ Redacted Document
- 1.3 ☐ Incoming Correspondence
 - 1.3.1 ☐ Amendment
 - 1.3.2 ☐ Update

2. ☐ Administrative Technical

- 2.1 ☐ Proposed Regulation
- 2.2 ☐ Proposed Tolerance
- 2.3 ☐ Exempt from Certification (*Color additive only*)

3. ☐ Chemistry

- 3.1 ☐ Identity
- 3.2 ☐ Use and Technical Effect
- 3.3 ☐ Labeling
- 3.4 ☐ Manufacturing Method
- 3.5 ☐ Residues
- 3.6 ☐ Specifications
- 3.7 ☐ Exposure Estimates
- 3.8 ☐ Studies
 - 3.8.1 ☐ Stability
 - 3.8.2 ☐ Intended Effect
 - 3.8.3 ☐ Migration
 - 3.8.4 ☐ Other Studies
- 3.9 ☐ Methods
- 3.10 ☐ References
 - 3.10.1 ☐ Literature Publications
 - 3.10.2 ☐ Other (including unpublished, etc.)

4. ☐ Safety

- 4.1 ☐ Toxicology Narrative
- 4.2 ☐ Studies
 - 4.2.1 ☐ Genetic Toxicity Tests
 - 4.2.2 ☐ Short Term Toxicity Studies Rodents
 - 4.2.3 ☐ Short Term Toxicity Studies Non-Rodents
 - 4.2.4 ☐ Subchronic Toxicity Studies Rodents
 - 4.2.5 ☐ Subchronic Toxicity Studies Non-Rodents
 - 4.2.6 ☐ One-Year Toxicity Studies Non-Rodents
 - 4.2.7 ☐ Chronic Toxicity Studies Rodents
 - 4.2.8 ☐ Carcinogenicity Studies Rodents

4. Safety (Continued)

4.2 Studies (Continued)

- 4.2.9 ☐ Combined Chronic Toxicity/ Carcinogenicity Studies Rodents
- 4.2.10 ☐ In Utero Exposure Phase for Addition to Carcinogenicity Studies Rodents
- 4.2.11 ☐ Reproduction Studies
- 4.2.12 ☐ Developmental Toxicity Studies
- 4.2.13 ☐ Immunotoxicity Studies
- 4.2.14 ☐ Metabolism and Pharmacokinetic Studies
- 4.2.15 ☐ Neurotoxicity Studies
- 4.2.16 ☐ Human Studies
- 4.2.17 ☐ Dermal Studies
- 4.2.18 ☐ Ocular Studies
- 4.2.19 ☐ Other Studies

4.3 ☐ References

- 4.3.1 ☐ Literature Publications
- 4.3.2 ☐ Other (including unpublished, etc.)

5. ☐ Environmental

- 5.1 ☐ Environmental Assessment
- 5.2 ☐ Claim of Categorical Exclusion
- 5.3 ☐ Confidential Environmental Information
- 5.4 ☐ Studies
- 5.5 ☐ References

6. ☐ Other (Information in original submission that does not fall under any of the above subfolders)

PART VII - SIGNATURE

Signature of Responsible Official, Agent or Attorney

Printed Name and Title

Date (mm/dd/yyyy)

PART VIII - LIST OF ATTACHMENTS

List your attached files or documents containing your petition or master file, forms, updates, or amendments and other pertinent information. Clearly identify the attachment with appropriate descriptive file names (or titles for paper documents), preferably as suggested in the guidance associated with this form. When submitting paper documents, enter the inclusive page numbers of each portion of the document below.

Element Number/Folder Location (see Part VI above)	Name of Attachment	Page Number(s) for Paper Copy Only

Add Continuation Page

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