COLOR ADDITIVE PETITION SUBMISSION				IISSION	Form Approval: OMB No. 0910-0016 Expiration Date: 11/30/2006 See Reverse for OMB Statement			
DEPARTMENT OF HEALTH AND HUMAN SERVIC				ES		FOR FDA USE ONLY		
FOOD AND DRUG ADMINISTRATION APPLICATION TO MARKET A NEW USE OF A COLOR AI (Title 21, Code of Federal Regulations, 71)				DDITIVE	PETITION TYPE	PETITION NUMBER	RECEIVED DATE	
APPLICANT INFORMATION								
1. NAME OF APPLICANT 2. DATE OF SUBMISSION							SUBMISSION	
3. TELEPHONE NO. (Include Area Code)				4. FACSIMILE (FAX) NO. (Include Area Code)				
5. APPLICANT ADDRESS (Number, Street, City, Country, and ZIP Code or Mail Code) Number and Street Street Address				6. AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP code, Telephone & FAX number) IF APPLICABLE Name Agent Name				
City and State City State Code				Number and Street Agent Address				
Country			City and State City	ST Zip Code or Mail Code ST Zip				
Zip Code or Mail Code				Telephone No. (Include area code)				
Zip_Code				Facsimile (Fax) No. (Include area code)				
SUBMISSION DESCRIPTION								
7. PETITION TITLE								
8. ADDITIVE FUNCTION 9. PRODUCT Food Drug Cosmetic								
10. FEE ENCLOSED □ Food use new listin □ Food use amendment □ Food use amendment (Attach check made out to: U.S. Food and Drug Administration)				nent (\$1,800)				
	CAL IDENTITIES							
CHEMICAL TYPE*	CAS NUMBER	CHEMICAL NAME			TRAD	E NAME (IF ANY)	STRUCTURE	
P	00000000							
L								
* D. Drimer	chemical C. Com	tituanta (including	idual monom			by producto, octobe	ata and ata)	
P – Primary	* P – Primary chemical, C – Constituents (including residual monomers, residual solvents, impurities, by-products, catalysts, and etc.)							

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)								
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								
SECTION A – C: Chemistry Section								
Chemistry Table of Contents (TOC)								
References								
18 • SECTION D: Safety Section**								
Safety of TOC								
Safety Summary								
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 								
□ Other Studies, e.g., Microbiology								
19 • SECTION E - I: Administrative Section*								
Administrative TOC Probable Exposure Information Exemption								
Image: Required Fee (See box 10 of page 1) Image: Proposed Tolerance Proposed Regulation 20 • SECTION J: Environmental Section								
Environmental TOC								
Environmental Assessment Categorical Exclusion								
Studies Studies								
References 21. SIGNATURE OF RESPONSIBLE OFFICIAL OR 22. TYPED NAME AND TITLE 23. DATE								
21. SIGNATURE OF RESPONSIBLE OFFICIAL OR 22. TYPED NAME AND TITLE 23. DATE AGENT 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)								
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College Park, MD 20740								
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