Form Approved: OMB No. 0190-0495, Approval Expires: May 31, 2012

Department of Health and Human Services
Food and Drug Administration

NOTIFICATION FOR A FOOD CONTACT SUBSTANCE FORMULATION

NOT FOR NEW USES OF FOOD CONTACT SUBSTANCES

AGENCY USE ONLY

DATE OF RECEIPT

When completed send the form and notification to:

NOTIFICATION CONTROL ASSISTANT
OFFICE OF FOOD ADDITIVE SAFETY
HFS-275
5100 PAINT BRANCH PARKWAY
COLLEGE PARK, MD 20740-3835

Enter the total number of pages in the Formulation Notification:

GENERAL INSTRUCTIONS

FCF - ☐☐☐☐☐☐

- This form is intended for use only to ascertain that all components of a food contact substance formulation may be legally marketed for their intended use.
- This form may not be used to request authorization for a new use of a food contact substance under section 409(h) of the Federal Food, Drug, and Cosmetic Act. New uses of food contact substances must be the subject of a notification under section 409(h) including an FDA Form 3480.
- You should include all information necessary to ascertain that each component of the formulation may be legally marketed for its intended use (technical effect). For example, if the basis for compliance is an effective notification, you should provide information establishing that you may rely on that notification.

Part I - GENERAL INFORMATION

A notification may not be submitted for a formulation unless all of the components of the formulation may be legally marketed for their intended use in contact with food. A notification for a food contact substance formulation should include all information necessary to establish that each compound in the formulation may be legally marketed. For example, additional information necessary to establish that each component of the formulation may be legally marketed for the intended use in contact with food should be attached. Any information referenced in a notification must be submitted to FDA prior to your notification. If you reference information from a third party that is located in other FDA files, provide a letter of authorization for such use, if necessary. For example, authorization is not necessary to reference publicly available information in FDA's files. If third party authorization is required, provide the name of the authorizing official for the third party and a mailing address.

Two copies of your complete notification must be submitted, each with a completed and signed original copy.

Part II - IDENTITY

Provide complete identity information for all components used to produce the food contact substance formulation. If a component (e.g. a reagent or solvent) is completely removed from the formulation as marketed, indicate so. Provide any relevant specifications in order to establish that all components of the formulation may be lawfully marketed.

Part III - INTENDED USE

If possible, use the food types listed in Table 1 of 21 CFR 176.170(c) to describe the types of food the food contact substance formulation will contact in its intended use. If possible, use the time and temperature conditions of use listed in Table 2 of 21 CFR 176.170(c) to describe the time and temperature conditions of use for the food contact substance formulation that is the subject of this notification.

Part Vl - LIST OF ATTACHMENTS

Attach additional sheets if there is not enough space to answer a question fully. Label each continuation sheet with the corresponding section heading. List these attachments, any test data or other data and any optional information included in the notification.

OPTIONAL INFORMATION

You may include any information that you want FDA to consider in evaluating this notification.

CONFIDENTIALITY OF INFORMATION

If you are claiming any information in this notification confidential you should submit a redacted copy of the notification. FDA may disagree regarding the disclosability of information claimed confidential.

SAMPLES

Provide a sample of the food contact substance formulation as intended for market.

PSC Graphics (301) 443-1090 EF

PART I - GENERAL INFORMATION

1a. PERSON SUBMITTING NOTICE

NAME OF AUTHORIZED OFFICIAL		POSITION	
COMPANY			
MAILING ADDRESS *(number and street)*			
CITY	STATE	ZIP CODE/POSTAL CODE	COUNTRY
TELEPHONE NUMBER	FAX NUMBER	E-MAIL ADDRESS	

☐ Please check here if E-Mail is your preferred method of communication.

1b. AGENT *(if applicable)*

NAME OF AUTHORIZED OFFICIAL		POSITION	
COMPANY			
MAILING ADDRESS *(number and street)*			
CITY	STATE	ZIP CODE/POSTAL CODE	COUNTRY
TELEPHONE NUMBER	FAX NUMBER	E-MAIL ADDRESS	

☐ Please check here if E-Mail is your preferred method of communication.

PART II - IDENTITY

SECTION A - IDENTIFICATION OF THE FOOD CONTACT SUBSTANCE

1. CHEMICAL IDENTITY

TRADE OR COMMON NAMES

2. FORMULATION COMPOSITION

CHEMICAL NAME AND MANUFACTURER		TYPICAL COMPOSITION (3)	MAXIMUM RESIDUAL (4)	CAS REG. NO. (5)	BASIS FOR COMPLIANCE (6)	TECHNICAL EFFECT (7)
CHEMICAL NAME (1)	MANUFACTURER (2)					
		%	%			
		%	%			
		%	%			
		%	%			
		%	%			
		%	%			
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		%	%			
		%	%			

PART II - INFORMATION ON IDENTITY, USE AND EXPOSURE *(continued)*

SECTION A - IDENTIFICATION *(continued)*

b. CHARACTERIZATION

List those characteristics of the formulation necessary to verify that the formulation may be lawfully marketed.

POLYMER PROPERTIES	VALUES

c. Describe the manufacturing process, including times and temperatures, and include chemical equations for all synthetic steps and side reactions. Describe any purification steps.

☐ Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number in Part IV of this form.

PART III - INTENDED USE

1. Describe the intended use of the food contact substance formulation, including maximum use levels (or thickness) in food contact materials, and types of food contact articles in which it is expected to be used (e.g., films, coatings, molded articles). State whether single or repeated use is intended. Provide maximum temperatures and times of food contact, refer to classifications in 21 CFR 176.170(c) Table 2 when possible.

☐ Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number in Part IV of this form.

2. List types of food expected to contact the formulation, with examples if known. Refer to classifications in 21 CFR 176.170(c) Table 1 when possible.

☐ Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number in Part IV of this form.

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

To assist FDA's review of physical and chemical properties data, please complete the following worksheet for data you provide and include it in the notification. Identify the property measured, the page of the notification on which the property appears, the value of the property, and the units in which the property is measured (as necessary). The measured properties should be for the food contact substance formulation. You are not required to submit this worksheet.

PROPERTY (a)	MARK (X) IF PROVIDED	PAGE NUMBER (b)	VALUE (c)	MEASURED OR ESTIMATE (M or E)
Physical state of the substance	☐		☐ (s) ☐ (l) ☐ (g)	☐ M ☐ E
Vapor pressure @ Temperature _____°C	☐		Torr	☐ M ☐ E
Density/relative density *(specify temperature)*	☐		g/cm^3	☐ M ☐ E
Solubility @ Temperature _____°C _____Solvent	☐		g/L	☐ M ☐ E
Solubility in water @ Temperature _____°C	☐		g/L	☐ M ☐ E
Melting Temperature	☐		°C	☐ M ☐ E
Boiling/sublimation temperature @ _____ torr pressure	☐		°C	☐ M ☐ E
Spectra	☐			☐ M ☐ E
Dissociation constant	☐			☐ M ☐ E
Particle size distribution	☐			☐ M ☐ E
Octanol/water partition coefficient	☐			☐ M ☐ E
Henry's Law constant	☐			☐ M ☐ E
pH _____ @ concentration	☐			☐ M ☐ E
Adsorption/coefficient	☐			☐ M ☐ E
Other - Specify	☐			☐ M ☐ E
Polymer specific *(If a range is applicable, indicate so)* % crystallinity of polymer	☐			☐ M ☐ E
Degree of orientation	☐			☐ M ☐ E
Thermal transitions of polymer *(i.e., Tg, Tm)*	☐			☐ M ☐ E
Density of polymer *(specify temperature)*	☐			☐ M ☐ E
	☐			☐ M ☐ E

PART IV - LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form and test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of the attachments. In the column below, enter the inclusive page numbers of each attachment. Notifiers need not list other components of their notification not specifically referenced to this form.

ATTACHMENT NAME	ATTACHMENT PAGE NUMBER(S)