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| 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 |
| When completed send the form and notification to: | DATE OF RECEIPT |
| 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: | |

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| GENERAL INSTRUCTIONS | FCF - <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |
| <ul style="list-style-type: none"> 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. | |

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| <p>Part I - GENERAL INFORMATION</p> <p>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.</p> <p>Two copies of your complete notification must be submitted, each with a completed and signed original copy.</p> <p>Part II - IDENTITY</p> <p>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.</p> <p>Part III - INTENDED USE</p> <p>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</p> | <p>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.</p> <p>Part VI - LIST OF ATTACHMENTS</p> <p>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.</p> <p>OPTIONAL INFORMATION</p> <p>You may include any information that you want FDA to consider in evaluating this notification.</p> <p>CONFIDENTIALITY OF INFORMATION</p> <p>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.</p> <p>SAMPLES</p> <p>Provide a sample of the food contact substance formulation as intended for market.</p> |
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| PUBLIC BURDEN STATEMENT |
| Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing 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, Center for Food Safety and Applied Nutrition Office of Food Additive Safety (0910-0495), 5100 Paint Branch Parkway (HFS-200), College Park, MD 20740-3835. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. |

PART I - GENERAL INFORMATION

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| 1a. PERSON SUBMITTING NOTICE | NAME OF AUTHORIZED OFFICIAL | | POSITION | |
| | COMPANY | | | |
| | MAILING ADDRESS <i>(number and street)</i> | | | |
| | 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.

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|---|--|------------|----------------------|----------------|
| 1b. AGENT <i>(if applicable)</i> | NAME OF AUTHORIZED OFFICIAL | | POSITION | |
| | COMPANY | | | |
| | MAILING ADDRESS <i>(number and street)</i> | | | |
| | 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 - 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 |
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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 Section 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 Section 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 Section 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 | <input type="checkbox"/> | | <input type="checkbox"/> (s) <input type="checkbox"/> (l) <input type="checkbox"/> (g) | <input type="checkbox"/> M <input type="checkbox"/> E |
| Vapor pressure @ Temperature _____ °C | <input type="checkbox"/> | | Torr | <input type="checkbox"/> M <input type="checkbox"/> E |
| Density/relative density (<i>specify temperature</i>) | <input type="checkbox"/> | | g/cm ³ | <input type="checkbox"/> M <input type="checkbox"/> E |
| Solubility @ Temperature _____ °C _____ Solvent | <input type="checkbox"/> | | g/L | <input type="checkbox"/> M <input type="checkbox"/> E |
| Solubility in water @ Temperature _____ °C | <input type="checkbox"/> | | g/L | <input type="checkbox"/> M <input type="checkbox"/> E |
| Melting Temperature | <input type="checkbox"/> | | °C | <input type="checkbox"/> M <input type="checkbox"/> E |
| Boiling/sublimation temperature @ _____ torr pressure | <input type="checkbox"/> | | °C | <input type="checkbox"/> M <input type="checkbox"/> E |
| Spectra | <input type="checkbox"/> | | | <input type="checkbox"/> M <input type="checkbox"/> E |
| Dissociation constant | <input type="checkbox"/> | | | <input type="checkbox"/> M <input type="checkbox"/> E |
| Particle size distribution | <input type="checkbox"/> | | | <input type="checkbox"/> M <input type="checkbox"/> E |
| Octanol/water partition coefficient | <input type="checkbox"/> | | | <input type="checkbox"/> M <input type="checkbox"/> E |
| Henry's Law constant | <input type="checkbox"/> | | | <input type="checkbox"/> M <input type="checkbox"/> E |
| pH _____ @ concentration | <input type="checkbox"/> | | | <input type="checkbox"/> M <input type="checkbox"/> E |
| Adsorption/coefficient | <input type="checkbox"/> | | | <input type="checkbox"/> M <input type="checkbox"/> E |
| Other - Specify | <input type="checkbox"/> | | | <input type="checkbox"/> M <input type="checkbox"/> E |
| Polymer specific (<i>If a range is applicable, indicate so</i>) % crystallinity of polymer | <input type="checkbox"/> | | | <input type="checkbox"/> M <input type="checkbox"/> E |
| Degree of orientation | <input type="checkbox"/> | | | <input type="checkbox"/> M <input type="checkbox"/> E |
| Thermal transitions of polymer (<i>i.e., T_g, T_m</i>) | <input type="checkbox"/> | | | <input type="checkbox"/> M <input type="checkbox"/> E |
| Density of polymer (<i>specify temperature</i>) | <input type="checkbox"/> | | | <input type="checkbox"/> M <input type="checkbox"/> E |
| | <input type="checkbox"/> | | | <input type="checkbox"/> M <input type="checkbox"/> E |

