

Department of Health and Human Services Food and Drug Administration <b>NOTIFICATION FOR NEW USE OF A FOOD CONTACT SUBSTANCE</b> <b>FOR NEW USES OF FOOD CONTACT SUBSTANCES</b>		<b>AGENCY USE ONLY</b>	
		DATE OF RECEIPT	
<b>When completed send the form and notification to:</b> 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 Premarket Notification:		DATE EFFECTIVE <i>(if effective)</i>	FCN NUMBER

### GENERAL INSTRUCTIONS

- You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. You should make reasonable estimates if you do not have actual data.
- Before you complete this form, you should read the appropriate guidance for completion of a notification for a food contact substance.

#### Part I - GENERAL INFORMATION

Only one new food contact substance (FCS) may be the subject of a particular notification. However, new multiple uses may be combined in a notification. A "new" use is one not otherwise authorized. If authorization is sought for use of multiple FCSs that are food additives, separate notifications should be submitted for each new use. Any accompanying information for a notification may be provided to FDA in a Food Additive Master File and referenced in a notification. 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. 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.

Completion of this form alone may not constitute a complete notification for a new use of an FCS. A notifier must also submit all data and information that forms the basis of the notifier's safety determination for the use that is the subject of the notification and any data and information required by regulation. Five copies of your complete notification must be submitted, each with a completed and signed original or copy of this form.

#### Part II - CHEMISTRY INFORMATION

Summarize all pertinent information concerning the FCS that is the subject of the notification. This should include: chemical identity, manufacturing process, physical properties and specifications, conditions of use, intended technical effect, and stability data. In addition to the summary information provided, your notification should include all supporting information or data. Also, include sufficient data to enable FDA to confirm your estimated daily intake resulting from the intended use of the substance. For information on recommendations on migration testing and presentation of the chemistry information see "Guidance for Industry: Preparation of Premarket Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations."

#### Part III - TOXICOLOGY INFORMATION

Include a list of toxicology studies considered key to the safety decision, discuss the potential mutagenicity and carcinogenicity of the notified substance and its constituents, determine the acceptable daily intake (ADI), as appropriate, and state the basis for your safety decision. This information should be consistent with the discussion in the Safety Narrative, which is described in the "Guidance for Industry: Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations."

#### Part VI - 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. Please do not attach information that can be included on the form.

#### OPTIONAL INFORMATION

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

#### CONFIDENTIALITY OF INFORMATION

By submitting a notification under section 409(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(h)), a notifier waives any claim to confidentiality for information necessary to describe the food contact substance and the intended conditions of use that are the subject of the notification. If you are claiming any information in this notification to be confidential you should designate the confidential material in writing, or otherwise mark the confidential material in the notification (e.g., by drawing a line around it), and submit a separate redacted copy of the notification. FDA may disagree regarding the disclosability of information claimed confidential.

#### PUBLIC BURDEN STATEMENT

Public reporting burden for this collection of information is estimated to average 25 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**









<b>1a. PERSON SUBMITTING NOTICE</b>	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. *(Please note that E-Mails may not be secure)*

<b>b. AGENT (if applicable)</b>	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. *(Please note that E-Mails may not be secure)*

**c. IDENTIFY THE MANUFACTURER/SUPPLIER FOR WHICH THIS FCN WILL BECOME EFFECTIVE**

2. If you had a prenotification consultation (PNC) or a correspondence letter (CTS) concerning this notification and FDA assigned a PNC or CTS number to the consultation, enter the number.			Mark (X) if None		<input type="checkbox"/>
3. Please site all food master files (FMFs) relevant to this FCN.			Mark (X) if None		<input type="checkbox"/>
4. If you previously submitted an FCN or FAP for this substance that is not effective, enter the FCN or FAP number assigned by FDA.			Mark (X) if None		<input type="checkbox"/>
5. List all effective notifications for the substance.  FDA maintains a list of effective notifications accessible through its internet site at:  <a href="http://www.cfsan.fda.gov/~dms/opa-fcn.html">http://www.cfsan.fda.gov/~dms/opa-fcn.html</a>			Mark (X) if None		<input type="checkbox"/>

**Part II - CHEMISTRY INFORMATION**

**SECTION A - IDENTIFICATION OF THE FOOD CONTACT SUBSTANCE**

*See Chemistry Recommendations, Sections II.A.1 through 4.*

1. Chemical Abstracts Service (CAS) name

2. CAS Registry Number

3. Trade or Common Name

4. Other Chemical Names (*IUPAC, etc.*)

5. Description

Provide a description of the FCS, including chemical formula(e), structure(s) and molecular weight(s). For FCSs that cannot be represented by a discrete chemical structure, such as new polymers, provide a representative chemical structure(s) and the  $M_w$  and  $M_n$ . For new copolymers, also provide the ratio of monomer units in the copolymer.

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

6. Characterization

Attach data, such as infrared (IR), ultraviolet (UV), nuclear magnetic resonance (NMR), mass spectra, or other similar data for identification of the FCS.

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



**Part II - CHEMISTRY INFORMATION (continued)**

**SECTION B - MANUFACTURE (continued)**

*See Chemistry Recommendations, Sections II.A.4.a through d.*

3. List impurities in the FCS including: the chemical names, CAS Reg. Nos., and typical and maximum residual levels (percent weight) in the FCS as it will be marketed. For FCSs that are polymers, include typical and maximum residual monomer concentrations. Provide supporting data including analytical methods and validation information.

CHEMICAL NAME	CAS REG. NO.	TYPICAL RESIDUAL (%)	MAXIMUM RESIDUAL (%)	Is residual expected to migrate from the final food contact material? †
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No

† If yes, ensure that exposures to these substances are addressed in Section II.G of this form. If no, provide an explanation below.

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

**Part II - CHEMISTRY INFORMATION (continued)**

**SECTION C - PHYSICAL/CHEMICAL SPECIFICATIONS**

*See Chemistry Recommendations, Section II.A.5 and 6*

Provide physical and chemical specifications for the FCS such as density, melting point, maximum impurity levels, and solubility in food simulants. Provide specification test results for at least three production batches of the FCS and attach methods for establishing compliance with specifications. For Values, provide minimum or maximum specification limits or a range, as appropriate.

1. For the FCS:

SPECIFICATION	VALUE

2. For polymeric FCSs provide the following additional information:

a. Polymer Properties and Test Results of Production Batches

Provide relevant physical data, such as molecular weight distribution, glass transition points, intrinsic or relative viscosities, melt flow indices, morphology, and crystallinity. Analytical methods should be included. Where appropriate, provide test results for at least three production batches of the FCS.

PROPERTY	MAX. VALUE	MIN. VALUE	INDIVIDUAL BATCH VALUES

**Part II - CHEMISTRY INFORMATION (continued)**

**SECTION C - PHYSICAL/CHEMICAL SPECIFICATIONS (continued)**

b. Molecular Weight Profile of the FCS

Provide a value for the maximum percentage of oligomeric species (not including residual monomers, reactants, or solvents) below 1000 Daltons and include supporting data and analytical methods.

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

**SECTION D - INTENDED USE**

*See Chemistry Recommendations, Sections II.B and II.C*

1. Describe the intended use of the FCS. Include maximum use level(s) in food-contact materials, types of food-contact articles with or in which the FCS is expected to be used (e.g., films, coatings, molded articles) and maximum thickness, as applicable. Indicate whether single or repeat use (or both) is intended:  Single Use  Repeat Use

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

2. a. For single-use articles, list the food types expected to contact the FCS, with examples if known. Refer to the food type classifications in the chemistry recommendations, when possible. Also provide maximum temperatures and times of food contact, referring to the conditions of use in the chemistry recommendations, when possible. ([click here for example](#))

USE	FOOD TYPE	CONDITION OF USE

**Part II - CHEMISTRY INFORMATION** *(continued)*

**SECTION D - INTENDED USE** *(continued)*

2. a. CONTINUED

USE	FOOD TYPE	CONDITION OF USE

b. For repeat-use articles, provide a typical use scenario. Include the highest intended use temperature, maximum food-contact time for the article, and typical amount of food contacted over the service lifetime of the article.

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



**Part II - CHEMISTRY INFORMATION** *(continued)*

3. State the intended technical effect of the FCS. Summarize data demonstrating that the FCS will achieve the intended technical effect. Specifically address the minimum amount required to achieve the intended technical effect. Include data as an attachment.

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

**SECTION E - STABILITY DATA**

*See Chemistry Recommendations, Section II.D.2*

1. Describe any degradation, decomposition or other chemical breakdown process (oxidation, photolysis, hydrolysis, etc.) that the FCS may undergo during either its intended use in the manufacture of a food-contact article or during migration testing (if performed) of a test plaque containing the FCS. If no degradation is expected, so state.

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

**Part II - CHEMISTRY INFORMATION**

2. List the breakdown products for the FCS and provide CAS names, CAS Reg. Nos., and structures, as appropriate. Address the amount of any breakdown products that migrate to food and ensure that exposures to these substances are addressed in Section II.G of this form.

SUBSTANCE NAME	CAS REG. NO.	SUBSTANCE NAME	CAS REG. NO.

STRUCTURE		STRUCTURE	
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SUBSTANCE NAME	CAS REG. NO.	SUBSTANCE NAME	CAS REG. NO.

STRUCTURE		STRUCTURE	
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Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number in Section VI of this form.

**Part II - CHEMISTRY INFORMATION** *(continued)*

**SECTION F - MIGRATION LEVELS IN FOOD**

*See Chemistry Recommendations, Sections II.D and Appendix II*

Summarize information on migration testing and/or calculations in the appropriate sections below for both the FCS and any migrants. A full report of all analytical testing, including detailed descriptions of methodology, raw data, and sample instrumental output (spectra, chromatograms, etc.) must be attached.

If exposure estimates are determined by assuming 100% migration to food, or through the use of other methods (*see Chemistry Recommendations II.D.5*), skip to Section II.F.2 and provide full details of all calculations.

For repeat-use articles, estimate migrant levels in food using migration testing and/or calculations which take into account the amount of food contacting the article over its service lifetime (*see Chemistry Recommendations, Appendix II, Part 4*).

**1. MIGRATION TESTING OPTION**

*See Chemistry Recommendations, Sections II.D.1 through II.D. 3*

a. Describe test specimen(s), including full composition (e.g., comonomer composition of base polymer, identities and concentrations of adjuvants, levels of residual monomer(s)), dimensions (thickness and surface area), and relevant base polymer properties (e.g., density,  $T_g$ ,  $T_m$ , % crystallinity). Indicate whether specimens were extracted by total immersion or exposed to solvent on a single side.

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

b. Identify food or food simulants employed, times and temperatures of extraction, volume of simulant used per extraction, and food simulant volume-to-specimen surface area ratio (e.g., 10% ethanol, conditions of use A [121°C/2 h, then 40°C/238 h], 200 mL of 10% ethanol solution per extraction, 10 mL/in<sup>2</sup>). If the food simulant volume-to-specimen surface area ratio is less than 10 mL/in<sup>2</sup>, provide evidence (e.g., turbidity or precipitation data) showing that saturation of the food simulant has not occurred.

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



**Part II - CHEMISTRY INFORMATION** *(continued)*

**SECTION F - MIGRATION LEVELS IN FOOD** *(continued)*

d. Provide a summary of method validation results. Give average percent recovery for all analytes, food or food simulants, and fortification (spiking) levels. Full details, including description of spiking procedure and calculations, must be included as an attachment.

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

**2. MIGRATION CALCULATION OPTION**

See [Chemistry Recommendations, Sections II.D.](#) for discussions on 100% migration calculations, [II.D.4](#) for information on FDA's migration database, and [II.D.5](#) for migration modeling.

Describe the basis of the mathematical approach used in estimating migration levels to food for the FCS or any migrants, such as impurities, monomers or breakdown products, in the FCS. Fully describe assumptions made in deriving the estimates and show all calculations.

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

**Part II - CHEMISTRY INFORMATION (continued)**

**SECTION G - ESTIMATED DAILY INTAKE (EDI)**

See *Chemistry Recommendations, Sections II.E and Appendix IV*

The EDI for the notified use must be calculated by the notifier for both the FCS and any migrants. The notifier is also responsible for providing cumulative EDIs (CEDIs) reflecting any previously regulated, notified, or otherwise authorized uses of the FCS. The notifier may wish to consult FDA to obtain this information prior to submitting a notification.

**1. SINGLE-USE ARTICLES**

Show representative calculations for the EDI for all migrants. Clearly describe the food-type distribution factors ( $f_T$ ) and consumption factors (CF) used in the calculations (*see Chemistry Recommendations Appendix IV*). If  $f_T$  and/or CF values other than those assigned by FDA are used, information supporting derivation and use of such factors must be attached. The following general equation is used to calculate an EDI:

$$\begin{aligned} \text{EDI} &= \text{DC} \times 3 \text{ kg food/p/d} \\ &= \text{CF} \times \langle M \rangle \times 3 \text{ kg food/p/d} \\ &= \text{CF} \times [(M_{\text{aq}})(f_{\text{aq}}) + (M_{\text{ac}})(f_{\text{ac}}) + (M_{\text{al}})(f_{\text{al}}) + (M_{\text{fat}})(f_{\text{fat}})] \times 3 \text{ kg/p/d} \end{aligned}$$

where: (aq) is aqueous, (ac) is acidic, (al) is alcoholic, and (fat) is fatty

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

**2. REPEAT-USE ARTICLES**

Using the migration levels to food determined in Section II.F.2 and the use scenario information described in Section II.D.2.b, show the calculations used for determining DC and EDI for the FCS and any migrants.

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



### Part III - SAFETY NARRATIVE

The safety narrative is an executive summary describing the scientific basis of your determination that the food contact substance (FCS) is safe under the conditions of use requested in this notification. Your safety narrative should address any negative information regarding the safety of the FCS and its constituents. Your safety narrative should summarize the chemistry and toxicology information that justify a conclusion that the intended use of the FCS is safe. Your safety narrative should also address the safety of any mutagenic or carcinogenic constituents of the FCS. Upper bound lifetime cancer risk levels and acceptable daily intake values should be included as appropriate. Instructions are provided in *Guidance for Industry - Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations, Section VI*. Do not provide detailed study summaries in the safety narrative. Such summaries and supporting documentation should be included in the Comprehensive Toxicology Profile(s) as an attachment to this notification (see *Guidance for Industry - Preparation of Premarket Notification for Food Contact Substances: Toxicology Recommendations, Section VII*).

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



**Part IV - ENVIRONMENTAL INFORMATION (21 CFR Part 25)**

All FCN submissions must contain either a claim of categorical exclusion under 21 CFR 25.32 or an environmental assessment (EA) under 21 CFR 25.40.

**A - CLAIM OF CATEGORICAL EXCLUSION**

1. Cite the specific section(s) of the CFR under which the categorical exclusion is claimed:

**21 CFR 25.32 (i)**

a. Is the FCS a component of a coating?  Yes  No

b. If no, the % of the FCS in the finished food-contact article is \_\_\_\_\_ and

c. The % of the total market volume that remains with the food-contact articles is \_\_\_\_\_

**21 CFR 25.32 (j)**

Is the FCS a component of a:

a. Repeat-use article?  Yes  No

b. Permanent or semi-permanent food-contact surface?  Yes  No

**21 CFR 25.32 (k)**

**21 CFR 25.32 (q)**

a. Is current FIFRA label attached?  Yes  No

b. Is the requested use essentially the same as the label?  Yes  No

If current FIFRA label has limitation on food-contact uses, provide a draft copy of a revised label you intend to submit to EPA to include food-contact uses.

**21 CFR 25.32 (r)**

2. Does your proposed food-contact use comply with the categorical exclusion criteria?  Yes  No  
If no, go to section B below.

3. To the best of your knowledge, are there any extraordinary circumstances that would require your submission of an EA? (see 21 CFR 25.21)  
If yes, go to section B below.  Yes  No

**B - ENVIRONMENTAL ASSESSMENT**

*See Environmental Recommendations*

1. If an EA is required, state that an EA has been prepared under 21 CFR 25.40, and is attached.

2. Environmental assessments are public documents and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

**Part V - CERTIFICATION**

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

SIGNATURE OF AUTHORIZED OFFICIAL OR AGENT

TITLE

DATE



## LIST OF EXAMPLES

2. a. For single-use articles, list the food types expected to contact the FCS, with examples if known. Refer to the food type classifications in chemistry guidance, when possible. Also provide maximum temperatures and times of food contact, referring to the conditions of use in chemistry guidance, when possible.

**Example:** A notifier wishes to obtain approval for the use of a polymer adjuvant, Adjuvant Y, in two specific olefin polymers for use with different food Types (see chemistry guidance) under different Conditions of Use (see chemistry guidance).

USE	FOOD TYPE	CONDITION OF USE
Adjuvant Y used in HDPE at levels not exceeding 0.3 wt.% of the finished polymer	Aqueous, Acidic and Low- Alcoholic (Types I, II, IVB, VIA, VIB and VIIB)	A through H
Adjuvant Y used in PP at levels not exceeding 0.2 wt.% of the finished polymer	Fatty Foods (Types III, IVA, V, VIIA, IX)	C through G

c. Summarize results of migration testing for each test specimen. Give individual and average migration values (mg/in<sup>2</sup>) for all analytes in each simulatant at all time points (an example of how the data should be presented is given below). In addition, provide sample calculations relating the instrumental output to reported migration values in mg/in<sup>2</sup>. For new polymers, provide a measure of oligomer migration and, if possible, characterize the individual low-molecular weight oligomer components.

**Example:** A notifier conducted a migration study to support the use of a polymer adjuvant, Adjuvant X, intended for use at a maximum level of 0.01 wt.% in LDPE. The example table below shows how the notifier might tabulate migration data obtained from sample plaques tested in 10% ethanol under conditions of use B.

### SUMMARY OF MIGRATION TESTING

TEST SAMPLE FORMULATION	MIGRANT	FOOD OR FOOD SIMULANT	TEMPERATURE AND TIME OF ANALYSIS	MIGRATION <i>(each replicate)</i>	AVERAGE MIGRATION <i>(average of replicates)</i>
LDPE containing 0.01 wt.% of Adjuvant X	Adjuvant X	10% ethanol	100°C analysis after 2 hours	0.012 mg/in <sup>2</sup> 0.011 mg/in <sup>2</sup> 0.021 mg/in <sup>2</sup>	0.015 mg/in <sup>2</sup>
			40°C analysis after 24 hours	0.015 mg/in <sup>2</sup> 0.014 mg/in <sup>2</sup> 0.022 mg/in <sup>2</sup>	0.017 mg/in <sup>2</sup>
			40°C analysis after 96 hours	0.017 mg/in <sup>2</sup> 0.017 mg/in <sup>2</sup> 0.023 mg/in <sup>2</sup>	0.019 mg/in <sup>2</sup>
			100°C analysis after 240 hours	0.020 mg/in <sup>2</sup> 0.021 mg/in <sup>2</sup> 0.023 mg/in <sup>2</sup>	0.021 mg/in <sup>2</sup>