Form Approved. O.M.B. No. 0910-0495 Approval Expires 11/30/2005

U.S. Food and Drug Administration

NOTIFICATION FOR NEW USE OF A FOOD CONTACT SUBSTANCE

FOR NEW USES OF FOOD CONTACT SUBSTANCES

When completed send this form and notification to	NOTIFICATION CONTROL ASSISTANT OFFICE OF FOOD ADDITIVE SAFETY HFS-275 5100 Paint Branch Parkway College Park, MD 20740-3835

AGENCY USE ONLY

Date of Receipt

Enter the total number of pages in the Premarket Notification	Date Effective (if effective)	FCN Number

GENERAL INSTRUCTIONS

FCN- ☐☐☐☐☐☐

- 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 use of an FCS may be the subject of a particular 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 submit a redacted copy of the notification. FDA may disagree regarding the disclosability of information claimed confidential.

Part I — GENERAL INFORMATION

1a. Person Submitting Notice

Name of authorized official	Position
Company	
Mailing address (number and street)	
City, State, ZIP Code, Country	

Telephone No.	Fax No.	E-Mail Address

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

b. Agent (if applicable)

Name of authorized official	Position
Company	
Mailing address (number and street)	
City, State, ZIP Code, Country	

Telephone No.	Fax No.	E-Mail Address

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

2. If you had a prenotification consultation (PNC) concerning this notification and FDA assigned a PNC Number to the consultation, enter the number. →		Mark (X) if none → ☐
3. If you previously submitted an FCN for this substance that is not effective, enter the FCN number assigned by FDA. →		Mark (X) if none → ☐
4. List all effective notifications for the substance. → FDA maintains a list of effective notifications accessible through its internet site at http://www.cfsan.fda.gov/~dms/opa-fcn.html.		Mark (X) if none → ☐

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.

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.

Part II — CHEMISTRY INFORMATION - CONTINUED

Section B - MANUFACTURE

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

1. List all reagents monomers, solvents, catalyst systems, purification aids, etc. used to manufacture the FCS, including their chemical names, CAS Registry Numbers, and functions in the manufacture of the FCS.

Chemical Name	CAS Reg. No.	Function

2. Describe the manufacturing process, including reaction conditions (e.g., times and temperatures), and include chemical equations and stoichiometry for all synthetic steps and side reactions. Describe any purification steps.

Part II — CHEMISTRY INFORMATION - CONTINUED

Section B - MANUFACTURE - Continued

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.

Chemical Name	CAS Reg No.	Typical Residual (%)	Maximum Residual (%)

Ensure that exposures to these substances are addressed in Section II.G of this form.

Part II — CHEMISTRY INFORMATION - CONTINUED

Section C - PHYSICAL/CHEMICAL SPECIFICATIONS
See Chemistry Recommendations Section II.A.5 and 6

1. For non-polymeric FCSs, provide physical/chemical specifications, such as density, melting point, maximum impurity levels, and solubility in food simulants.

Property	Value

2. In addition, provide the following relevant information for polymeric FCSs:

a. Polymer Properties and Specification 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 specification test results for at least three production batches of the FCS. Attach methods for establishing compliance with specifications.

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.

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. State whether single or repeated use is intended.

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 21 CFR 176.170(c) Table 1, when possible. Also provide maximum temperatures and times of food contact, referring to the conditions of use in 21 CFR 176.170(c) Table 2, 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 21 CFR 176.170(c) Table 1) under different Conditions of Use (see 21 CFR 176.170(c) Table 2).

FCS/Use	Food Type	Conditions 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

Part II — CHEMISTRY INFORMATION - CONTINUED

Section D - INTENDED USE
2.a. - Continued

FCS/Use	Food Type	Conditions 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.

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. Attach data.

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, state none.

Part II — CHEMISTRY INFORMATION - CONTINUED

2. List the breakdown products for the FCS and provide CAS names, CAS Reg. Nos., and structures, as applicable. 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	Structure

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 other 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, estimation of migrant levels in food using migration testing and/or calculations also takes into account the amount of food to contact 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), dimensions (thickness and surface area), and relevant base polymer properties (e.g., density, T_g, T_m, % crystallinity). For new polymers, provide levels of residual monomer(s) in the test specimen(s). Indicate whether specimens were extracted by total immersion or exposed to solvent on a single side.

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 [121ºC/2 h, then 40ºC/238 h], 200 mL of 10% ethanol solution per extraction, 10 mL/in²). If the food simulant volume-to-specimen surface area ratio is less than 10 mL/in², provide evidence (e.g., turbidity or precipitation data) showing that saturation of the food simulant has not occurred.

Section F - MIGRATION LEVELS IN FOOD - Continued

c. Summarize results of migration testing for each test specimen. Give individual and average migration values (mg/in²) for all analytes in each simulant 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/in². 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.

Example Table

Test Sample Formulation	Migrant	Food or Food Simulant	Temperature and time of analysis	Migration (each replicate)	Average Migration (average of replicates)
LDPE containing 0.01 wt.% of Adjuvant X	Adjuvant X	10% ethanol	100ºC analysis after 2 hours	0.012 mg/in² 0.011 mg/in² 0.021 mg/in²	0.015 mg/in²
			40ºC analysis after 24 hours	0.015 mg/in² 0.014 mg/in² 0.022 mg/in²	0.017 mg/in²
			40ºC analysis after 96 hours	0.017 mg/in² 0.017 mg/in² 0.023 mg/in²	0.019 mg/in²
			40ºC analysis after 240 hours	0.020 mg/in² 0.021 mg/in² 0.023 mg/in²	0.021 mg/in²

Part II — CHEMISTRY INFORMATION - CONTINUED

Section F - MIGRATION LEVELS IN FOOD - Continued

Summary of Migration Testing

Test Sample Formulation	Migrant	Food or Food Simulant	Temperature and time of analysis	Migration (each replicate)	Average Migration (average of replicates)

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.

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 other migrants, such as impurities, monomers or breakdown products, in the FCS. Fully describe any assumptions made in deriving the estimates and show all calculations.

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 other 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 OFAS to obtain this information prior to submitting a notification.

1. Single-use Articles

Summarize the values for weight-average migration (<M>), dietary concentration (DC), and estimated daily intake (EDI) for the FCS and any other 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:

EDI = DC x 3 kg food/p/d
= CF x <M> x 3 kg food/p/d
= CF x $[(M_{aq})(f_{aq})+(M_{ac})(f_{ac})+(M_{al})(f_{al})+(M_{fat})(f_{fat})]$ x 3 kg/p/d

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

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 other migrants.

Part III — TOXICOLOGY INFORMATION

The toxicology information requested in this part includes the safety narrative (Section A), a tabulation of relevant safety studies on the food contact substance (FCS) (Section B), information about the potential carcinogenicity and toxicity of constituent(s) (Section C), and a brief description of any other relevant information not included in the other sections (Section D). If an acceptable daily intake (ADI) has been calculated by the Agency for the FCS, do not complete the table for other relevant studies in Section B unless new data are available. In case the database is extensive for a constituent, contact FDA for guidance on preparing Section C. Do not provide detailed study summaries in any of the sections below, such summaries should be included in the Comprehensive Toxicology Profile(s) of your notification (see *Guidance for Industry- Preparation of Premarket Notification for Food Contact Substances: Toxicology Recommendations, Section VII).*

SECTION A - SAFETY NARRATIVE

In this section provide your safety narrative. Your safety narrative should summarize the information that justifies a conclusion that the intended use of the FCS is safe. Your safety narrative should also address any mutagenic or carcinogenic constituents of the FCS. Appropriate upper bound lifetime risk levels for carcinogenic constituents should be included. Instructions are provided in *Guidance for Industry- Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations, Section VI.*

Part III — TOXICOLOGY INFORMATION - CONTINUED

SECTION B - RELEVANT SAFETY STUDIES ON THE FCS OR FOOD ADDITIVE

Tabulate all of the relevant safety studies on the FCS or food additive, using the table provided. Relevant safety studies include both unpublished and published genetic toxicity tests, carcinogenicity studies, and other relevant safety studies (e.g., subchronic studies, chronic toxicity studies, reproduction and developmental toxicity studies, and other specialized studies such as immunotoxicity and neurotoxicity studies). Metabolism, pharmacokinetic, and epidemiological studies should also be included, if relevant. Generally, only oral carcinogenicity studies should be listed, but carcinogenicity studies by routes other than oral administration should be included if systemic toxicity is observed.

GENETIC TOXICITY STUDIES

Substance	Test System	Concentrations or Dose Levels	Results [a]	Summary/Study Locations [b]

[a] Positive, negative, or equivocal

[b] Identify the locations (e.g., page numbers) of the corresponding summary in the CTP section and full study reports or published articles.

OTHER RELEVANT SAFETY STUDIES

Substance	Duration	Route	Species/ Sex	No. of Animals/ Group	Dose Levels	Toxicological Effects		NOEL [b] (mg/kg b.w./d)	Summary/ Study Locations [c]
						LOEL [a] (mg/kg b.w./d)	End Points or Target Organs		

[a] Lowest Observable Effect Level

[b] List highest No Observable Effect Level (NOEL) from each listed study. If a NOEL can not be established, write "None" in this column.

[c] Identify the locations (e.g., page numbers) of their corresponding summary in the CTP section and full study reports or published articles.

Part III — TOXICOLOGY INFORMATION - CONTINUED

SECTION B - RELEVANT SAFETY STUDIES ON THE FCS OR FOOD ADDITIVE -CONT'D

CARCINOGENICITY STUDIES [a]								
Substance	**Duration**	**Route**	**Species/ Sex**	**No. of Animals/ Group**	**Dose Levels**	**Neoplastic Lesions [b]**	**Non-Neoplastic Lesions [b]**	**Summary/ Study Locations [c]**

[a] The chronic phase of the combined chronic toxicity and carcinogenicity studies should be listed separately in the table for OTHER RELEVANT SAFETY STUDIES.

[b] Identify the treatment-related neoplastic and/or non-neoplastic lesions. If no treatment-related lesions are identified in the study, indicate "No" here.

[c] Identify the locations (e.g., page numbers) of their corresponding summary in the CTP section and full study reports or published articles.

SECTION C - INFORMATION ABOUT POTENTIAL CARCINOGENICITY AND TOXICITY OF CONSTITUENT(S)

1. Tabulate all of the unpublished and published genetic toxicity tests and carcinogenicity tests for each constituent. Generally, only oral carcinogenicity studies should be listed, but carcinogenicity studies by routes other than oral administration should be included if systemic toxicity is observed.

GENETIC TOXICITY STUDIES				
Substance	**Test System**	**Concentrations or Dose Levels**	**Results [a]**	**Summary/Study Locations [b]**

[a] Positive, negative, or equivocal

[b] Identify the locations (e.g., page numbers) of the corresponding summary in the CTP section and full study reports or published articles.

Part III — TOXICOLOGY INFORMATION - CONTINUED

SECTION C - INFORMATION ABOUT POTENTIAL CARCINOGENICITY AND TOXICITY OF CONSTITUENT(S) - CONT'D

CARCINOGENICITY STUDIES								
Substance	**Duration**	**Route**	**Species/ Sex**	**No. of Animals/ Group**	**Dose Levels**	**Neoplastic Lesions** [a]	**Non-Neoplastic Lesions** [a]	**Summary/ Study Locations** [b]

[a] Identify the treatment-related neoplastic and/or non-neoplastic lesions. If no treatment-related lesions are identified in the study, indicate "No" here.

[b] Identify the locations (e.g., page numbers) of their corresponding summary in the CTP section and full study reports or published articles.

2. Is any constituent known to be a potent toxicant? If so, indicate the nature of the toxicity, the test system, and the dose level at which toxicity was observed.

Part III — TOXICOLOGY INFORMATION - CONTINUED

SECTION D - OTHER RELEVANT TOXICOLOGY DATA OR INFORMATION

Provide a brief description of other data and information, which are not mentioned above, that are relevant to the safety evaluation. A description of the number and types of supportive studies and evaluations of structural similarities of the FCS or constituents to known toxicants are examples of the kinds of information that might be appropriate to include in this section. It would also be appropriate to mention in this section, pertinent hazard assessments or risk analyses from other regulatory agencies and/or international bodies here.

Part IV — ENVIRONMENTAL IMPACT OF FOOD CONTACT SUBSTANCE (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 of the CFR under which the categorical exclusion is claimed (21 CFR 25.32 (i), (j), (k), (q), or (r) _____

2. Does your proposed food-contact use comply with the categorical exclusion criteria? ☐ Yes ☐ No

3. To the best of your knowledge are there any extraordinary circumstances that would require your submission of an EA? ☐ Yes ☐ No

B - ENVIRONMENTAL ASSESSMENT

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

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

Part VI — 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, as 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 in this form.

Attachment name	Attachment page number(s)

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