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Food Contact Review

April 18, 2024

Mete Plastik Sanayi ve Ticaret A.S
Beylikduzu OSB Mah. Mermerciler
Sanayi Sitesi 10. Cad. No:4
Beylikduzu, Istanbul TR-34524
Turkey

RE: Your Food Contact Substance – Random Copolymer Polyprophlene Container

Dear Sir or Madam,

We present our report and recommendations regarding the food contact article ("FCA") you have submitted for our review. Based on the information provided to Registrar Corp, it appears that your food contact substance ("FCS") component may be identified as poly(ethylene-co-propylene). Accordingly, this review describes the regulations promulgated for this substance by the United States ("U.S.") Food and Drug Administration ("FDA") for incorporation into your food contact article. Please confirm that this is accurate for your product.

After review of your food contact substance, it appears that your product may not require premarket notification to FDA so long as your substances comply with FDA regulations indicated in the following review. Please review Section 2 of this report for further information on your product's component.

Our recommendations for this particular FCS are detailed. Please feel free to contact us after you have reviewed this material to discuss our findings in detail.

Very truly yours,

Corey Todd

Anna Benevente
Senior Regulatory Specialist

Corey Todd
Senior Regulatory Specialist

Section 1: Overview of Definitions and Requirements for a Food Contact Substance

The following definitions may be of use to you in interpreting this report:

1.1 **Definition of Food Contact Surfaces –** Food contact surfaces are any surfaces of equipment, utensils, containers, or wrappings that come in direct contact with food. Food contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food contact surfaces shall be maintained to protect food from being contaminated by any source including unlawful indirect food additives.[1] Seams on food contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.[2]

1.2 **Definition of Food Contact Article ("FCA") –** The FCA is the finished film, bottle, dough hook, tray, or other item that is formed out of the food contact materials.[3]

1.3 **Definition of Food Contact Materials ("FCM") –** FCMs are made with FCSs and usually other substances. It is often, but not necessarily, a mixture such as an antioxidant in a polymer. The composition may be variable.[4] An example of an FCM may be plastic, glass, rubber, and other such materials that are used to make a final product that comes in contact with food.

1.4 **Definition of Food Contact Substances ("FCS") –** Once known as indirect food additives, the United States ("U.S.") Food and Drug Administration ("FDA") now refers to these materials as FCSs. FDA defines FCSs as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.[5] The regulatory status of a FCM is dictated by the regulatory status of each individual FCS that comprises the article. It is the responsibility of the manufacturer of an FCS to ensure that FCMs comply with the specifications and limitations in all applicable authorizations. When reviewing your composite formulations to determine compliance, consider each authorization to be composed of three parts: the *identity* of the substance, *specifications*

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[1] 21 CFR 110.40(a)
[2] 21 CFR 110.40(b)
[3] "Food Ingredients and Packaging Terms," *FDA*, available at https://www.fda.gov/food/food-ingredients-packaging/food-ingredient-packaging-terms
[4] "Food Ingredients and Packaging Terms," *FDA*, available at https://www.fda.gov/food/food-ingredients-packaging/food-ingredient-packaging-terms
[5] 21 USC 348(h)(6)

including purity or physical properties, and *limitations* on the conditions of use. The individual substance that is reasonably expected to migrate to food because of its intended use in the FCM shall be covered by one of the following:[6]

1.4.1 Title 21 Code of Federal Regulations ("CFR") – The requirement for premarket approval in section 409 of the Food, Drug, and Cosmetic Act ("FD&C Act") in 1958 resulted in the development of a petition process by which a person could request approval of a food additive for an intended use. The approval resulted in a regulation listed in Title 21 of the CFR. Components of a food packaging material used in compliance with a regulation in Title 21 of the CFR need no further FDA review.

1.4.2 GRAS Status – "GRAS" is an acronym for the phrase **G**enerally **R**ecognized **A**s **S**afe.[7] Under sections 201(s) and 409 of the FD&C Act, any substance that is intentionally added to food is a food additive and is subject to premarket review and approval by FDA. A substance is **excluded** from this requirement if it is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.[8]

The use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.

- Under 21 CFR 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information.
- Under 21 CFR 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.

There must be evidence that the substance is safe under the conditions of its intended use. FDA has defined "safe" as a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use. The specific data and information that demonstrates safety depends on the

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[6] "Determining the Regulatory Status of Components of a Food Contact Material," *FDA*, available at https://www.fda.gov/food/packaging-food-contact-substances-fcs/determining-regulatory-status-components-food-contact-material

[7] 21 CFR 170.203

[8] 81 FR 54960 at 54982

characteristics of the substance, the estimated dietary intake, and the population that will consume the substance.[9]

1.4.3 Prior Sanction Letter – Prior sanctioned substances are those substances whose use in contact with food is the subject of a letter issued by FDA or USDA before 1958 offering no objection to a specific use of a specific substance.[10]

1.4.4 Threshold of Regulation ("TOR") Exemption – Threshold of regulation exemptions verify that an FCS is exempted from a petition or a food contact notification ("FCN") as a food additive because it becomes a component of food at levels that are below the threshold of regulation. A substance used in an FCA may be exempted by FDA from the need of an FCN or a petition as a food additive if:[11]

- The substance has not been shown to be a carcinogen and there is no reason to suspect that it is a carcinogen, and
- The substance presents no other health or safety concerns because the use in question has been shown to result in a very low concentration (≤0.5 ppb) or the substance is currently regulated for direct addition into food and the dietary exposure is at or below 1% of the acceptable daily intake as determined by safety data, and
- The substance has no technical effect in or on the food to which it migrates, and
- The substance use has no significant adverse impact on the environment

1.4.5 Effective Food Contact Notification ("FCN") – FDA will accept FCNs for unapproved uses of food additives that meet the definition of an FCS. FDA believes that a substance that is GRAS or prior sanctioned for its intended use in contact with food also may be an FCS and may be the subject of an FCN even though authorization under the FCN process is not required for the FCS use. Section 409(h)(2)(C) of the FD&C Act states that an FCN is effective for the manufacturer, and the conditions of use identified in the notification is not effective for a similar or identical substance produced or prepared by a manufacturer other than a manufacturer identified in the prior notification.[12] FCNs are proprietary to the

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[9] 21 CFR 170.3(i)
[10] "Food Ingredients and Packaging Terms," *FDA*, available at https://www.fda.gov/food/food-ingredients-packaging/food-ingredient-packaging-terms
[11] 21 CFR 170.39(a)
[12] "Guidance for Industry: Preparation of Food Contact Notifications (Administrative)," *FDA*, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-food-contact-notifications-administrative

manufacturer for which the notification is effective; therefore, the FCN must be obtained from that manufacturer.

1.4.6 **Food Additive Petition ("FAP") –** The FCN appears to be the primary vehicle through which FDA grants clearance for an FCS; however, FDA may determine that submission and review of a FAP is necessary to provide adequate assurance of safety, or where FDA and a sponsor agree that a petition may be submitted.[13]

As described above, the overall regulatory status of an FCM is dictated by the regulatory status of each individual substance that comprises the material. If each component of a product meets one of the above conditions for its intended use, it appears that premarket notification to FDA is not required prior to marketing. If a component of a formulation does not meet one of the conditions described above for its intended use, an FCN or FAP must be submitted for the component. Please note that Registrar Corp does not currently assist with the submission of FCNs or FAPs to FDA.

In addition, please note the following state level requirements in California:

1.5 **California Proposition 65 ("Prop 65") –** With few exceptions, the State of California mandates that "no person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual."[14]

On August 30, 2016, amendments were adopted that modified the regulations pertaining to the warning requirements. These amendments repealed all regulations found in Article 6 of the Act and become operative on August 30, 2018. These requirements apply to consumer products, defined as "any article, or component part thereof, including food, that is produced, distributed, or sold for the personal use, consumption or enjoyment of a consumer."[15] The manufacturer, producer, packager, importer, supplier, or distributor of a product must comply either by affixing a label to the product bearing a warning or by providing a written notice directly to the authorized agent for a retail seller who is subject to the Act.[16] Consumer product exposure warnings must be prominently displayed on a label, labeling, or sign, and must be displayed with such conspicuousness as compared with other words, statements, designs or devices on

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[13] "Guidance for Industry: Preparation of Food Contact Notifications (Administrative)," *FDA*, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-food-contact-notifications-administrative

[14] Safe Drinking Water and Toxic Enforcement Act of 1986, tit. 27 § 25249.6

[15] Cal. Code Regs. tit. 27 § 25600.1(d)

[16] Cal. Code Regs. tit. 27 § 25600.2(b)

the label, labeling, or sign, as to render the warning likely to be read and understood by an ordinary individual under customary conditions of purchase or use.[17] The format and content of the warning will vary depending on the nature of the toxin and the type of exposure (e.g. consumer product, food, alcoholic beverage).[18]

Please note that this requirement applies to substances that have been intentionally added (i.e. ingredient) as well as those substances that may become incorporated as a result of environmental factors and manufacturing processes. The list of chemicals subject to these requirements can be found here: https://oehha.ca.gov/proposition-65/proposition-65-list.

If you intend to distribute your product in California, it would be prudent to determine whether any substance present on the Prop 65 list is incorporated into your product's formulation or packaging. If you determine that your product contains a substance present on this list, please ensure that your product label bears the appropriate warning as specified in regulation.

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[17] Cal. Code Regs. tit. 27 § 25601(c)

[18] Cal. Code Regs. tit. 27 § 25602, § 25603, § 25607

Section 2: Analysis of Your Food Contact Substances

The questionnaire you completed for Registrar Corp at the onset of this review states that your FCA is a container intended for food storage. s are plastic glasses and boxes, used in the packaging of food and beverage products. The questionnaire completed by your firm provides the following information regarding the FCS found in your formulation:

- Random Copolymer Polyprophlene [sic] CAS No. 9010-79-1

Please refer to Appendix I of this report for a copy of your completed Food Contact Substance Questionnaire. Please review the following information regarding the food contact substance in your product:

2.1 Random Copolymer Polyprophlene [sic] CAS No. 9010-79-1 – Based upon the CAS number provided, it appears that your FCS may be identified as "poly(ethylene-co-propylene)"[19] Other synonyms Include Ethene-Propene Copolymer and Ethylene-Propylene Copolymer.[20]

Please confirm that your FCS may be properly identified as "poly(ethylene-co-propylene)" or either of the synonyms referenced. If your substance may be properly identified in this manner, it appears that this substance would be classified as an "olefin polymer." FDA characterizes olefin basic copolymers as:[21]

> *Olefin basic copolymers manufactured by the catalytic copolymerization of two or more of the monomers ethylene, propylene, butene-1, 2-methylpropene-1, and 2,4,4-trimethylpentene-1 shall contain not less than 85 weight-percent of polymer units derived from ethylene and/or propylene;*

Please ensure that your FCS meets this description for olefin basic copolymers. Basic olefin polymers may contain optional adjuvant substances as specified in 21 CFR 177.1520. Please inform Registrar Corp if your substance contains any additional adjuvant substances, so that we may further assist you.

FDA states that olefin polymers may be safely used as articles or components of articles intended for use in contact with food when in compliance with the specifications found

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[19] "Inventory of Food Contact Substances Listed in 21 CFR: POLY(ETHYLENE-CO-PROPYLENE)," *FDA*, available at https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=IndirectAdditives&id=POLYETHYLENECOPROPYLENE

[20] "Inventory of Food Contact Substances Listed in 21 CFR: POLY(ETHYLENE-CO-PROPYLENE)," *FDA*, available at https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=IndirectAdditives&id=POLYETHYLENECOPROPYLENE

[21] 21 CFR 177.1520(a)(3)(i)(c)(*1*)

in 21 CFR 177.1520(c). FDA has established specific specifications to which this FCS must conform:[22]

- Density must be within the following range : 0.85 – 1.00g/cm^3
- Maximum extractable fraction (expressed as percent by weight of the polymer) in *N* -hexane must be 5.5% at 50°C.
- Maximum soluble fraction (expressed as percent by weight of polymer) in xylene must be 30% at 25°C.

The olefin polymer described in this section may be used as a component of the food-contact surface of any article that is the subject of a regulation in 21 CFR Parts 174 [Indirect Food Additives-General], 175 [Adhesives and Components of Coatings], 176 [Paper and Paperboard Components], 177 [Polymers], 178 [Adjuvants and Production Aids] and 179.45 [Irradiation]. When used as such, it shall comply with any specifications and limitations prescribed by such regulation for the article in the finished form in which it is to contact food.[23]

Please ensure that your component conforms to the regulations outlined above. Please refer to Appendix II of this report for the analytical methods for determining whether your olefin polymer conforms to the aforementioned specifications. If your FCS conforms, then it appears to be appropriate for use in your food contact article. If you determine that your FCS component does not conform to the regulations outlined above, please inform Registrar Corp so we may better assist you.

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[22] 21 CFR 177.1520(c)(3.1a)
[23] 21 CFR 177.1520(f)

Section 3: Additional Information Regarding FCNs and FAPs

Based on the information provided, it appears that your product may not require an FCN for its intended use. **We present the following information in the event that your product does not conform to the specifications described in Section 2 of this report.**

FDA has published guidance that clarifies when an FCN is appropriate and when the use of the FCS will necessitate a FAP. The FCN appears to be the primary vehicle through which FDA grants clearance for an FCS; however, FDA may determine that submission and review of a FAP is necessary to provide adequate assurance of safety, or where FDA and a sponsor agree that a petition may be submitted. Therefore, simultaneous submission of a FAP and a notification for the same use of an FCS by the same person will not be permitted.[24]

3.1 Food Contact Notification Requirement – FCNs are required only for new uses of FCSs that are food additives. Although a notification is not required for an FCS that is determined to be GRAS or prior sanctioned for its intended use in contact with food, some companies may choose to notify the Agency in order to clarify the regulatory status of such substances. Manufacturers may also use FCNs to notify FDA of new uses of FCSs that are GRAS or prior sanctioned.

Unlike food additive regulations and threshold of regulation exemptions, approvals under the FCN process are proprietary. This is because Section 409(h)(1)(C) of the FD&C Act states that an FCN is effective only for the manufacturer and substance identified in the notification. Thus, any person wishing to rely on an FCN needs to demonstrate that the FCS being marketed has been manufactured or supplied by the manufacturer identified in the FCN and is being used under the conditions that are the subject of the FCN.[25] This may seem a trivial point, but it is important since the manufacturer for which the FCN is effective does not need to be the actual manufacturer of the FCS but can also be a supplier who is purchasing the substance and distributing it for the intended use. If a notifier is not careful in defining the entities for which the FCN is effective, the proprietary approval received in a successful FCN may not be applied to the intended company.

3.2 Food Contact Notification Process – The FCN process is initiated when a submission, prepared by the notifier, arrives at the Office of Food Additive Safety. A notification control assistant logs the submission and assigns it a notification number. The

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[24] "Guidance for Industry: Preparation of Food Contact Notifications (Administrative)," *FDA*, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-food-contact-notifications-administrative

[25] "Regulatory Report: FDA's Food Contact Substance Notification Program," *FDA*, available at http://wayback.archive-it.org/7993/20171114191238/https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ucm064161.htm

submission is then distributed to a review team for assignment. The review team consists of a consumer safety officer, a chemist, a toxicologist, and an environmental scientist.

A "phase one" review meeting is held within the first three weeks after receipt of the FCN to ensure that the basic data and informational elements are present and that the submission meets the administrative requirements set forth in the FD&C Act and FDA regulations. If the submission is complete, it is accepted, and FDA will send an acknowledgment letter. The acknowledgment letter establishes the date of receipt of the notification, which indicates when the 120-day FCN review period began and that the review team is entering into "phase two" review.

During "phase two," the team evaluates the safety of the FCS as it is proposed for use. If there are no concerns during the "phase two" review, the FCN automatically becomes effective on the 120-day date, and the consumer safety officer sends a letter to the notifier confirming the effective date. Information about the notification is then added to the Inventory of Effective Premarket Notifications for Food Contact Substances posted on CFSAN's web page.[26]

3.3 Food Additive Petition – As mentioned earlier in Sections 1.4.6 and 3 of this report, a FAP instead of an FCN may be required to obtain regulatory approval of an FCS in some cases. FDA requires the submission of a petition in either of the following situations:[27]

1) When the use of the FCS will increase the cumulative estimated daily intake ("CEDI") of the FCS from both food and food-contact uses to a level equal to or greater than 1 part per million (ppm) (i.e., 3 mg/person/day) for a substance that is not a biocide or, in the case of a biocide (e.g., it is intended to exempt microbial toxicity) to a level equal to or greater than 200 parts per billion ("ppb") (i.e., 0.6 mg/person/day), or

2) When existing data include one or more bioassays on the FCS that the Agency has not reviewed already and such studies are not clearly negative for carcinogenicity.

When a FAP for an FCS is submitted without prior consultation with the Agency, FDA will conduct a prefiling review of the petition to determine whether the petitioned use

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[26] "Regulatory Report: FDA's Food Contact Substance Notification Program," *FDA*, available at http://wayback.archive-it.org/7993/20171114191238/https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ucm064161.htm

[27] 21 CFR 170.100(c)

should instead be the subject of an FCN. If so, FDA will not file the petition and will so notify the petitioner.[28]

In general, the following elements are included in FAPs to support the approval of a substance for its intended use:[29]

- The identity and composition of the additive
- Proposed use
- Use level
- Data establishing the intended effect
- Quantitative detection methods
- Estimated exposure from the proposed use (in food, drugs, cosmetics, or devices, as appropriate)
- Full reports of all safety studies
- Proposed tolerances (if needed)
- Environmental information (as required by the National Environmental Policy Act (NEPA), as revised[30]
- Fee (for color additive petitions only)
- Ensure that consistent information is presented throughout all sections of the petition, including those pertaining to: chemistry, toxicology, environmental science, and any other pertinent studies (e.g., microbiology)

FDA provides the following contact for further information in determining whether a FAP is necessary:[31]

FDA/Center for Food Safety and Applied Nutrition
HFS-200
5001 Campus Drive
College Park, MD 20740-3835

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[28] "Guidance for Industry: Preparation of Food Contact Notifications (Administrative)," *FDA*, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-food-contact-notifications-administrative

[29] "Guidance for Industry: Questions and Answers About the Petition Process," *FDA*, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-about-food-additive-or-color-additive-petition-process

[30] 62 FR 40570; July 29, 1997

[31] "Guidance for Industry: Questions and Answers About the Petition Process," *FDA*, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-about-food-additive-or-color-additive-petition-process

Email: premarkt@fda.hhs.gov

FDA encourages pre-petition consultations to assist industry determining whether a FAP is required and if so, in ensuring that the petition will meet FDA's requirements for establishing safe conditions of use.[32] Under section 409(h)(3)(A) of the Act, FDA and a notifier may agree that a petition may be submitted to authorize the use of an FCS. If a notification was submitted prior to this agreement, the notification shall be deemed to be withdrawn in accordance with 21 CFR 170.103. FDA recommends that persons wishing to submit a petition contact the Agency prior to making such a submission to obtain FDA's agreement. Under 21 CFR 171.1(i)(1), FDA will decline to file a FAP for a use of an FCS that the Agency believes should be the subject of an FCN under section 409(h) of the Act.[33]

If you decide to submit a FAP, it may be prudent to arrange for a pre-petition consultation by contacting the Office of Food Additive Safety:[34]

Office of Food Additive Safety
Division of Petition Review (HFS-265)
5001 Campus Drive
College Park, Maryland, 20740-3835
240-402-1267

3.4 **TOR Exemption Request –** FDA permits a substance used in an FCA to be exempted from FCN or FAP requirements if the use in question has been shown to result in a very low concentration (≤0.5 ppb) (TOR exemption request). If use of the aforementioned components conforms to these requirements, a TOR exemption request may be appropriate.

As a reminder, Registrar Corp does not assist with FCN, FAP, or TOR submissions to FDA. Should you require clarification, please contact the Office of Food Additive Safety for assistance in this matter.

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[32] "Guidance for Industry: Pre-Petition Consultations for Food Additives and Color Additives," *FDA*, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-pre-petition-consultations-food-additives-and-color-additives

[33] "Guidance for Industry: Preparation of Food Contact Notifications (Administrative)," *FDA*, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-food-contact-notifications-administrative

[34] "Guidance for Industry: Pre-Petition Consultations for Food Additives and Color Additives," *FDA*, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-pre-petition-consultations-food-additives-and-color-additives

Section 4: Summary

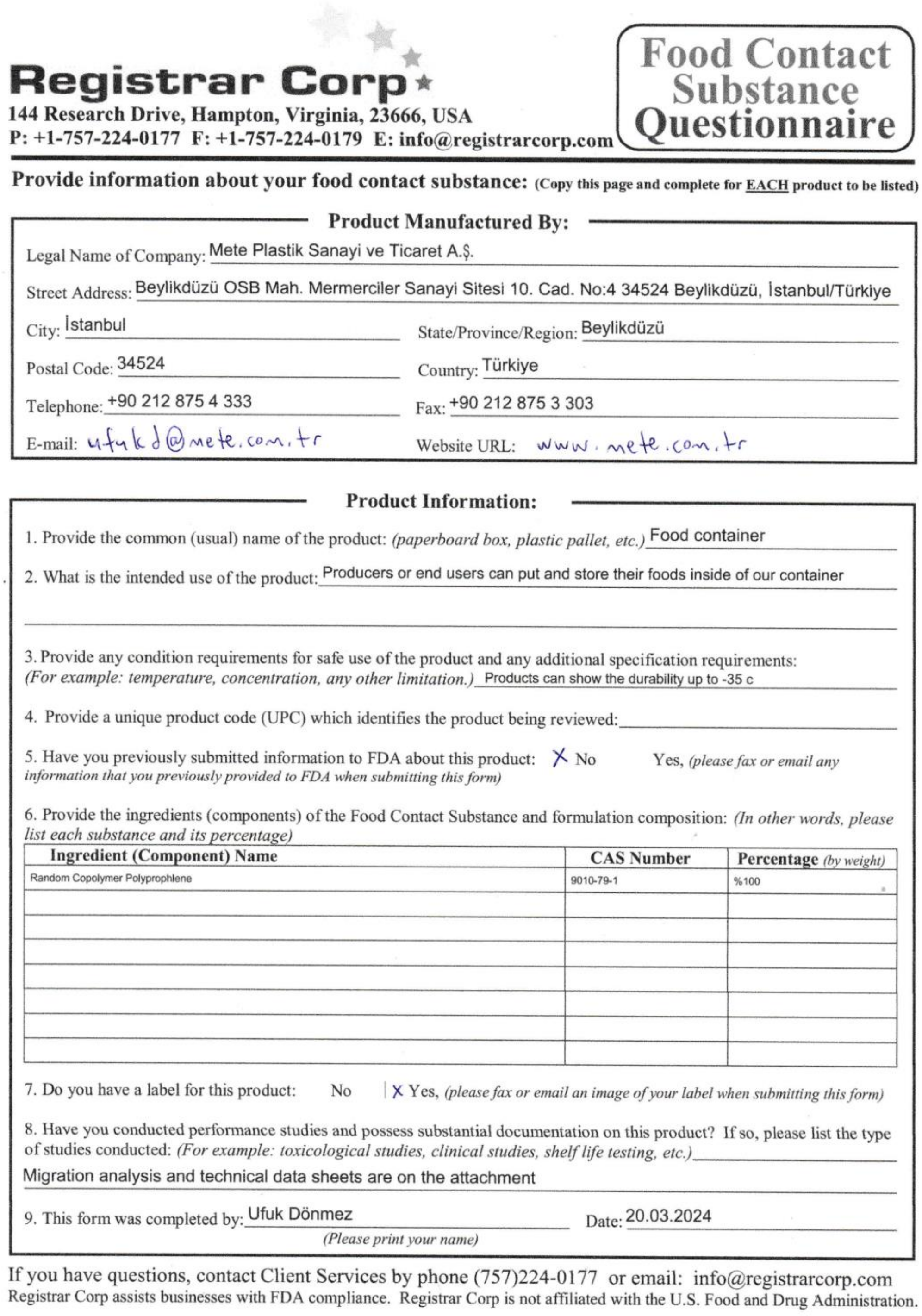
Based on the information provided to Registrar Corp, it appears that your FCS component may be identified as poly(ethylene-co-propylene). Based on the information provided to Registrar Corp, it does not appear that your FCS require notification to FDA prior to introduction to the US market. If you determine that your product does not comply with the specifications outlined in Section 2 of this report, please advise Registrar Corp so that we may further assist you.

If you determine that we have not appropriately identified this substance in your product based on the information you provided, please inform Registrar Corp so we may better assist you.

Disclaimer

Certain components of food contact substance analysis are necessarily subjective. Our recommendations constitute our advice concerning prudent compliance with U.S. FDA regulations, and do not constitute a guaranty of acceptance by the U.S. Food and Drug Administration. Registrar Corp does not offer legal advice and is not responsible for consequential damages resulting from any product rejection as a result of improper labeling or ingredients. For a legal opinion concerning construction or application of the regulations or statutes, we recommend retaining an attorney.

Appendix I
Completed Food Contact Substance Questionnaire



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Food Contact Substance Questionnaire

Provide information about your food contact substance: (Copy this page and complete for EACH product to be listed)

Product Manufactured By:

Legal Name of Company: Mete Plastik Sanayi ve Ticaret A.Ş.

Street Address: Beylikdüzü OSB Mah. Mermerciler Sanayi Sitesi 10. Cad. No:4 34524 Beylikdüzü, İstanbul/Türkiye

City: İstanbul

State/Province/Region: Beylikdüzü

Postal Code: 34524

Country: Türkiye

Telephone: +90 212 875 4 333

Fax: +90 212 875 3 303

E-mail: ufukd@mete.com.tr

Website URL: www.mete.com.tr

Product Information:

1. Provide the common (usual) name of the product: *(paperboard box, plastic pallet, etc.)* Food container

2. What is the intended use of the product: Producers or end users can put and store their foods inside of our container

3. Provide any condition requirements for safe use of the product and any additional specification requirements: *(For example: temperature, concentration, any other limitation.)* Products can show the durability up to -35 c

4. Provide a unique product code (UPC) which identifies the product being reviewed:

5. Have you previously submitted information to FDA about this product: [✓ No] Yes, *(please fax or email any information that you previously provided to FDA when submitting this form)*

6. Provide the ingredients (components) of the Food Contact Substance and formulation composition: *(In other words, please list each substance and its percentage)*

Ingredient (Component) Name	CAS Number	Percentage *(by weight)*
Random Copolymer Polyprophlene	9010-79-1	%100

7. Do you have a label for this product: No [✓ Yes], *(please fax or email an image of your label when submitting this form)*

8. Have you conducted performance studies and possess substantial documentation on this product? If so, please list the type of studies conducted: *(For example: toxicological studies, clinical studies, shelf life testing, etc.)*
Migration analysis and technical data sheets are on the attachment

9. This form was completed by: Ufuk Dönmez *(Please print your name)* Date: 20.03.2024

If you have questions, contact Client Services by phone (757)224-0177 or email: info@registrarcorp.com
Registrar Corp assists businesses with FDA compliance. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Appendix II
Analytical Methods for Olefin Polymers (21 CFR 177.1520(d))

(d) The analytical methods for determining whether olefin polymers conform to the specifications prescribed in this section are as follows, and are applicable to the basic polymer in film form not exceeding 4 mils in thickness. The film to be tested shall be cut into approximately 1-inch squares by any convenient method that avoids contamination by dust, dirt, or grease (Note: Do not touch samples with bare fingers--use forceps to hold or transfer samples).

(1) *Density*. Density shall be determined by ASTM method D1505-68 (Reapproved 1979), "Standard Test Method for Density of Plastics by the Density-Gradient Technique," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(2) *Melting point or softening point* –

(i) *Melting point*. The melting point shall be determined by ASTM method D2117-82, "Standard Test Method for Melting Point of Semicrystalline Polymers by the Hot Stage Microscopy Method," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (d)(1) of this section.

(ii) *Softening point*. The softening point shall be determined by ASTM method E28-67 (Reapproved 1982), "Standard Test Method for Softening Point by Ring-and-Ball Apparatus," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (d)(1) of this section.

(3) *Maximum extractable fraction in n-hexane* –

(i) *Olefin copolymers described in paragraph (a)(3)(ii) of this section, polypropylene, and poly(methylpentene)*. A sample is refluxed in the solvent for 2 hours and filtered at the boiling point. The filtrate is evaporated and the total residue weighed as a measure of the solvent extractable fraction.

(*a*) *Apparatus*.

(*1*) Erlenmeyer flasks, 250-milliliter, with ground joint.

(*2*) Condensers, Allihn, 400-millimeter jacket, with ground joint.

(*3*) Funnels, ribbed 75-millimeter diameter, stem cut to 40 millimeters.

(*4*) Funnels, Buchner type, with coarse-porosity fritted disc, 60-millimeter diameter.

(*5*) Bell jar for vacuum filtration into beaker.

(*b*) *Reagent*. *n-* Hexane, commercial grade, specific gravity 0.663-0.667 (20 deg. C/20 deg. C), boiling range 66 deg. C-69 deg. C, or equivalent.

(*c*) *Procedure*. Weigh 1 gram of sample accurately and place in a 250-milliliter Erlenmeyer flask containing two or three boiling stones. Add 100 milliliters of solvent, attach the flask to the condenser (use no grease), and reflux the mixture for 2 hours. Remove the flask from the heat, disconnect the condenser, and filter rapidly, while still hot, through a small wad of glass wool packed in a short-stem funnel into a tared 150-millimeter beaker. Rinse the flask and filter with two 10-milliliter portions of the hot solvent, and add the rinsings to the filtrate. Evaporate the filtrate on a stream bath with the aid of a stream of nitrogen. Dry the residue in a vacuum oven at 110 deg. C for 2 hours, cool in a desiccator, and weigh to the nearest 0.0001 gram. Determine the blank on 120 milliliters of solvent evaporated in a tared 150-milliliter beaker. Correct the sample residue for this blank if significant. Calculation:

$$\frac{\text{Grams of residue}}{\text{Grams of sample} \times 100} = \text{Percent extractable with n-hexane.}$$

(ii) *Olefin copolymers described in paragraph (a)(3)(i) of this section and polyethylene.* A preweighed sample is extracted at 50 deg. C for 2 hours and filtered. The filtrate is evaporated and the total residue weighed as a measure of the solvent extractable fraction. Alternatively, the sample is reweighed after the extraction period to give a measure of the solvent extractable fraction. The maximum *n* -hexane-extractable fraction may be determined by the methods set forth in paragraphs (d)(3)(ii)(*a*) through (d)(3)(ii)(*i*) of this section.

(*a*) *Extraction apparatus*. Two-liter, straight-walled, Pyrex (or equivalent) resin kettles, fitted with three-hole ground-glass covers are most convenient for this purpose. The cover is fitted with a thermometer, a gas-tight stirrer driven by an air motor or explosion-proof electric motor, and a reflux condenser. The kettle is fitted with an electric heating mantle of appropriate size and shape, which is controlled by a variable-voltage transformer.

(*b*) *Evaporating apparatus*. Rapid evaporation of large volumes of solvent requires special precautions to prevent contamination by dust. This is facilitated by a special "gas" cover consisting of an inverted flat Pyrex crystallizing dish of an appropriate size (190 millimeters * 100 millimeters) to fit a 1-liter beaker. Through the center of the dish are sealed an inlet tube for preheated, oxygen-free nitrogen, and an outlet tube located 1 inch off center. Nitrogen is fed from the supply source through a coil of 1/4-inch stainless steel tubing immersed in the same steam bath used to supply heat for solvent evaporation. All connections are made with flexible tetrafluoroethylene tubing.

(*c*) *Reagents* –

(*1) n-Hexane*. Spectrograde *n-* hexane.

(*2) Nitrogen*. High-purity dry nitrogen containing less than 10 parts per million of oxygen.

(*d*) *Procedure*. Transfer 2.5 grams (accurately weighed to nearest 0.001 gram) of the polymer to the resin kettle. Add 1 liter of solvent and clamp top in position. Start water flowing through jacket of the reflux condenser and apply air pressure to the stirring motor to produce vigorous agitation. Turn on heating jacket with transformer set at a predetermined voltage to bring the temperature of the contents to 50 deg. C within 20-25 minutes. As the thermometer reading approaches 45 deg. C-47 deg. C, reduce the voltage to the predetermined setting that will just maintain the temperature at 50 deg. C. Do not overshoot the prescribed temperature. Should this occur discard the test and start afresh. Exactly 2 hours after the solvent temperature has reached 50 deg. C, disconnect the heater, remove the resin kettle from the heating jacket, and decant the solvent, while still warm, through a coarse filter paper placed on top of a fritted-glass funnel, collecting the filtrate in a tared, glass-stoppered Erlenmeyer flask of 1-liter capacity. Determine the weight of the filtrate recovered to the nearest gram. Recovery should be at least 90 percent of the original solvent. Losses due to evaporation during heating and filtering have been found not to exceed 10 percent. Transfer about half of the solvent filtrate to a 1-liter beaker placed on an opening in the steam bath and immediately cover with the special "gas" cover, the inlet tube of which has been attached with flexible tetrafluoroethylene tubing to a source of high-purity nitrogen in series with a stainless steel heating coil immersed directly in the body of the steam bath. Maintain a positive flow of warm nitrogen gas throughout the evaporation of the solvent, adding the remainder of the filtrate from the Erlenmeyer flask as the evaporation proceeds. When the volume of the solvent has been reduced to about 50 milliliters, transfer the concentrated liquid to a previously tared weighing dish of suitable size. Wash the beaker twice with 20-30 milliliter portions of warm solvent, adding the washings to the weighing dish while continuing to evaporate the remainder of the solvent under the gas cover with its flow of warm nitrogen directed toward the center of the dish. In the event that an insoluble residue that cannot be removed with warm solvent remains in the beaker, it may be necessary to heat with a small amount of a higher boiling solvent such as benzene or toluene, transferring these washings to the weighing dish before final evaporation to dryness. Transfer the weighing dish with its residue to a vacuum desiccator, and allow it to remain overnight (at least 12 hours), after which the net weight of the dry residue is determined to the nearest 0.0001 gram. Correct the result for any solvent blank equivalent to the nonvolatile matter determined to be contained in the amount of solvents used in the test.

(*e*) *Extraction apparatus for alternate method*. Two-liter extraction vessel, such as a resin kettle or round bottom flask, fitted with an Allihn condenser (size C), a 45/50 male joint with a Teflon sleeve, and a Teflon coated stir bar. Water bath maintained at 49.5 deg. C +/- 0.5 deg. C containing a submersible magnetic stirrer motor with power supply. Other suitable means of maintaining temperature control, such as electric heating mantles, may be used provided that the temperature range can be strictly maintained.

(*f*) *Sample basket (Optional)*. A perforated stainless steel cylindrical basket that is approximately 1.5 inches in diameter, 1.6 inches high, and has perforations of 0.125 inches in diameter for 33 holes/in ^{2}, or 40 percent open area. The basket should pass freely through the 45/50 female joint of the extraction flask. A No. 6-32 stainless steel eye-bolt is attached to the lid for positioning the basket in the extraction vessel. The positioning rod, approximately 18 inches long and made from 1/16 inch outside diameter 316 stainless steel welding rod or equivalent and hooked at both ends, is used to position the basket in the extraction apparatus.

(*g*) *Vacuum oven.* Capable of maintaining 80 deg. C +/-5 deg. C and a minimum of 635 millimeters of mercury pressure.

(*h*) *Reagents. n* -Hexane, reagent or spectrograde, aromatic free (less than 1 milligram per liter), minimum 85 percent *n* -hexane. This reagent may be reused until it contains a maximum of 1.5 grams polyolefin extractables or has been used for 12 determinations.

(*i*) *Procedure.* Assemble the extraction vessel, condenser, and magnetic stir bar. Add *n* -hexane (1 liter) to the extraction vessel and clamp the assembly into a water bath set at 49.5 deg. C +/-0.5 deg. C. Start the water flowing through the jacket of the reflux condenser. Adjust the air flow through the stirring motor to give a smooth and uniform stir rate. Allow the *n* -hexane to preheat for 1 hour to bring the temperature to 49.5 deg. C+/-0.5 deg. C. Temperature is a critical factor in this analysis and it must not vary more than 1 deg. C. If the temperature exceeds these limits, the test must be discontinued and restarted. Blown, compression molded, or extrusion cast films can be tested. Ideally, the film should be prepared by the same process as will be used with the production resin. Using gloves and metal tweezers to avoid sample contamination, cut about 2.7 grams of the prepared film (4 mils or less in thickness) into about 1-inch squares using clean sharp scissors. Proceed with Option 1 or 2.

Option 1. Using tweezers and noting the number of film pieces, transfer 2.5 grams (accurately weighed to 0.1 milligram) of polymer to the extraction vessel. Extract the film sample for 2 hours. Allow the vessel to cool and filter the contents through a fritted porcelain funnel. Wash the film pieces with fresh *n* -hexane, aspirate to dryness, and transfer, using tweezers, to a beaker. Recount the film pieces to verify that none were lost during the transfer. Place the beaker in the vacuum oven for 2 hours at 80 deg. C +/-5 deg. C. After 2 hours, remove and place in a desiccator to cool to room temperature (about 1 hour). After cooling, reweigh the film pieces to the nearest 0.1 milligram. Calculate the percent hexane-extractables content from the weight loss of the original sample. Multiply the result by 0.935 and compare with extraction limits in paragraph (c) of this section. Repeat the above procedure for successive samples.

Option 2. Transfer 2.5+/-0.05 grams of the prepared 1-inch film sections into a tared sample basket and accurately weigh to the nearest 0.1 milligram. Carefully raise the condenser until the hook on the positioning rod is above the neck of the 2-liter extraction vessel. The basket should be totally below the level of *n* -hexane solvent. Extract the sample resin film for 2 hours and then raise the basket above the solvent level to drain momentarily. Remove the basket and rinse the contents by immersing several times in fresh *n* -hexane. Allow the basket to dry between rinsings. Remove the excess solvent by briefly blowing the basket with a stream of nitrogen or dry air. Place the basket in the vacuum oven for 2 hours at 80 deg. C +/-5 deg. C. After 2 hours, remove and place in a desiccator to cool to room temperature (about 1 hour). After cooling, reweigh the basket to the nearest 0.1 milligram. Calculate the percent hexane extractables content from the weight loss of the original sample. Multiply the result by 0.935 and compare with extraction limits in paragraph (c) of this section. Repeat the above procedure for successive samples. The same solvent charge should remain clear and can be used for at least 12 determinations. Applications of solvent reuse should be confirmed for each resin type before use.

(4) *Maximum soluble fraction in xylene* –

(i) *Olefin copolymers described in paragraph* (*a*)(*3*)(*ii*) *of this section, polypropylene, and poly* (*methylpen-tene*). A sample is dissolved completely in xylene by heating and stirring in a bottle with little free space. The solution is allowed to cool without stirring, whereupon the insoluble portion precipitates and is filtered off; the total solids content of the filtrate is then determined as a measure of the soluble fraction.

(*a*) *Apparatus*

(*1*) Pyrex (or equivalent) reagent bottle, 125-milliliter, glass-stoppered.

(*2*) Heating mantle of size for 150-milliliter beaker (or suitable aluminum block to fit the 125-milliter bottle described in paragraph (d)(4)(i)(*a*)(*1*) of this section.

(*3*) Magnetic stirrer for use under the heating mantle (combination magnetic stirrer and hotplate may be used if aluminum block is used in place of heating mantle).

(*4*) Variable-voltage transformer, 7.5 amperes.

(*5*) Tetrafluoroethylene-resin-coated stirring bar, 1-inch long.

(*6*) Constant temperature water bath maintained at 25 deg. C+/-0.5 deg. C.

(*7*) *Aluminum* dishes, 18 millimeters * 60 millimeters, disposable.

(*8*) Funnel, Buchner type, with coarse-porosity fritted disc, 30-60 millimeter diameter.

(*b*) *Reagent.* Xylene with antioxidant. Dissolve 0.020 gram of phenyl-[beta]- naphthylamine in 1 liter of industrial grade xylene having specific gravity 0.856-0.867 (20 deg. C/20 deg. C) and boiling range 123 deg. C-160 deg. C.

(*c*) *Procedure*. Weigh 1 to 2 grams of sample to the nearest 0.001 gram and place in a 125-milliliter Pyrex reagent bottle containing a 1-inch long tetrafluoroethylene-resin-coated stirring bar. Add 100 milliliters of solvent, set the stopper in lightly, and place the bottle in the heating mantle or aluminum block maintained at a temperature of 120 deg. C, and stir with a magnetic stirrer until the sample is completely dissolved. Remove the bottle from the heat and allow it to cool 1 hour in the air, without stirring. Then place the bottle in a water bath maintained at 25 deg. C +/-0.5 deg. C, and allow to stand 1 hour without stirring. Next, remove the bottle from the water bath, shake, and pour part of the contents into the coarse-porosity fritted-glass funnel. Apply suction, and draw 30-40 milliliters of filtrate through, adding more slurry to the funnel, and catching the filtrate in a large test tube. (If the slurry is hard to filter, add 10 grams of diatomaceous earth filter aid to the bottle and shake vigorously just prior to the filtration.) Pipet a suitable aliquot (preferably 20 milliliters) of the filtrate into a tared aluminum disposable dish. Place the dish on a steam bath covered with a fresh sheet of aluminum foil and invert a short-stemmed 4-inch funnel over the dish. Pass nitrogen (heated if desired) down through the funnel at a rate sufficient to just ripple the surface of the solvent. When the liquid has evaporated, place the dish in a vacuum oven at 140 deg. C and less than 50 millimeters mercury pressure for 2 hours. Cool in a desiccator and weigh. (Note: If the residue value seems high, redry in the vacuum oven for one-half hour to ensure complete removal of all xylene solvent.) Calculation:

$$\frac{\textit{Grams}\text{ of residue}}{\text{Grams of sample}} \times \frac{100\text{ milliters}}{\text{volume of aliquot in milliliters}} \times 100 = \textit{Percent}\text{ soluble in xylene}$$

(ii) *Olefin copolymers described in paragraph* (*a*)(*3*)(*i*) *of this section and polyethylene.* A sample is extracted in xylene at reflux temperature for 2 hours and filtered. The filtrate is evaporated and the total residue weighed as a measure of soluble fraction.

(*a*) *Apparatus –*

(*1*) *Extraction apparatus.* Two-liter, straight-walled Pyrex (or equivalent) resin kettles, fitted with ground-glass covers, are most convenient for this purpose. The cover is equipped with a thermometer and an efficient reflux condenser. The kettle is fitted with an electric heating mantle of appropriate size and shape which is controlled by a variable-voltage transformer.

(*2*) *Constant temperature water bath.* It must be large enough to permit immersion of the extraction kettle and set to maintain 25 deg. C +/-0.1 deg. C.

(*3*) *Evaporating apparatus.* Gas cover consisting of a flat Pyrex crystallizing dish (190 millimeters * 100 millimeters) inverted to fit over a 1-liter beaker with 8-millimeter gas inlet tube sealed through center and an outlet tube 1 inch off center. The beaker with gas cover is inserted in an electric heating mantle equipped with a variable-voltage transformer. The outlet tube is attached to an efficient condenser mounted on a receiving flask for solvent recovery and having an outlet for connection to an aspirator pump. The heating mantle (with the beaker) is mounted on a magnetic stirring device. An infrared heat lamp is mounted vertically 3-4 inches above the gas cover to prevent condensation of the solvent inside the cover. Make all connections with flexible tetrafluoroethylene tubing.

(*b*) *Reagents –*

(*1*) *Xylene*. American Chemical Society reagent grade that has been redistilled through a fractionating column to reduce the nonvolatile residue.

(*2*) *Nitrogen*. High-purity dry nitrogen containing less than 10^{4} parts per million oxygen.

(*c*) *Procedure*. Transfer 5 grams +/-0.001 gram of sample to the resin kettle, add 1,000 milliliters (840 grams) of xylene, and clamp top in position after inserting a piece of glass rod to prevent bumping during reflux. Start water flowing through the jacket of the reflux condenser and apply full voltage (115 volts) to the heating mantle. When the xylene starts to boil, reduce the voltage to a level just sufficient to maintain reflux. After refluxing for at least 2 hours, disconnect the power source to the mantle, remove the kettle, and allow to cool in air until the temperature of the contents drops to 50 deg. C, after which the kettle may be rapidly cooled to 25 deg. C-30 deg. C by immersing in a cold water bath. Transfer the kettle to a constant temperature bath set to maintain 25 deg. C +/-0.1 deg. C, and allow to equilibrate for a least 1 hour (may be left overnight if convenient). Break up any precipitated polymers that may have formed, and decant the xylene solution successively through a fast filter paper and then through a fritted-glass filter into a tared 1-liter Erlenmeyer flask, collecting only the first 450 milliliters--500 milliliters of filtrate (any attempt to collect more of the xylene solution usually results in clogging the filter and risking losses). Reweigh the Erlenmeyer flask and calculate the weight of the filtrate obtained to the nearest 0.1 gram. Transfer the filtrate, quantitatively, from the Erlenmeyer flask to the 1-liter beaker, insert the beaker in its heating mantle, add a glass-coated magnetic stirring bar, and mount the gas cover in place, connecting the inlet tube to the nitrogen source and the outlet to the condenser of the receiving flask. Start a flow of nitrogen (2 to 3 liters per minute) into the gas cover and connect an aspirator to the receiver using a free-flow rate equivalent to 6-7 liters of air per minute. With the infrared lamp on, adjust the voltage to the heating mantle to give a distillation rate of 12-13 milliliters per minute when the magnetic stirrer is revolving just fast enough to promote good boiling. When the volume of solvent in the beaker has been reduced to 30-50 milliliters, transfer the concentrated extractive to a suitable weighing dish that has been previously tared (dry). Rinse the beaker twice with 10-20 milliliter portions of fresh xylene, adding the rinsings to the weighing dish. Evaporate the remainder of the xylene on an electric hotplate set at low heat under the gas cover with a stream of nitrogen directed toward the center of the dish. Avoid any charring of the residue. Transfer the weighing dish to a vacuum desiccator at room temperature and allow to remain under reduced pressure for at least 12 hours (overnight), after which determine the net weight of the residue to the nearest 0.0001 gram. Correct the result for nonvolatile solvent blank obtained by evaporating the equivalent amount of xylene under identical conditions. Calculate the weight of residue originally present in the total weight of solvent (840 grams), using the appropriate factor based on the weight of filtrate evaporated.

(5) *Viscosity average molecular weight olefin copolymers described in paragraphs* (*a*)(*3*) (*iii*) *and* (*iv*) *of this section*. The viscosity average molecular weight shall be determined from the kinematic viscosity (using ASTM method D445-74, "Test for Kinematic Viscosity of Transparent and Opaque Liquids" (Revised 1974), which is incorporated by reference; copies are available from American Society for Testing and Materials (ASTM), 100 Barr Harbor Dr., West

Conshohocken, Philadelphia, PA 19428-2959, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.) of solutions of the copolymers in solvents and at temperatures as follows:

(i) Olefin polymers described in paragraph (a)(3)(iii) of this section in decahydronaphthalene at 135 deg. C.

(ii) Olefin polymers described in paragraph (a)(3)(iv) of this section in tetrachloroethylene at 30 deg. C.

(6) *Mooney viscosity--olefin copolymers described in paragraph (a)(3)(iii) of this section*. Mooney viscosity is determined by ASTM method D1646-81, "Standard Test Method for Rubber--Viscosity and Vulcanization Characteristics (Mooney Viscometer)," which is incorporated by reference (the availability of this incorporation by reference is given in paragraph (d)(1) of this section), using the large rotor at a temperature of 100 deg. C, except that a temperature of 127 deg. C shall be used for those copolymers whose Mooney viscosity cannot be determined at 100 deg. C. The apparatus containing the sample is warmed for 1 minute, run for 8 minutes, and viscosity measurements are then made.

(7) *Melt flow index*. The melt flow index of olefin polymers described below shall be determined by ASTM method D-1238-82, "Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer," which is incorporated by reference in accordance with 5 U.S.C. 552(a). The availability of this incorporation by reference is given in paragraph (d)(1) of this section. The olefin polymers and test conditions and procedures are as follows:

List of polymers	Conditions/procedures
Olefin copolymers described in paragraph (a)(3)(i)(c)(2) of this section	Condition L, procedure A.
Olefin copolymers described in paragraph (a)(3)(v) of this section	Condition E, procedure A.
Olefin polymers described in paragraph (a)(2)(ii) of this section	Condition E, procedure A.
Olefin polymers described in paragraph (a)(3)(vi) of this section	Condition E, procedure A.

(8) *Melting peak temperature*. The melt temperature of the olefin polymers described in paragraph (a)(3)(ii) of this section shall be determined by ASTM method D 3418-82, "Standard Test Method for Transition Temperatures of Polymers by Thermal Analysis," which is

incorporated by reference in accordance with 5 U.S.C. 552(a). The availability of this incorporation by reference is given in paragraph (d)(1) of this section.

(9) *Intrinsic viscosity*. The intrinsic viscosity of the olefin polymers described in paragraph (a)(3)(ii) of this section shall be determined by ASTM method D 1601-78, "Standard Test Method for Dilute Solution Viscosity of Ethylene Polymers," which is incorporated by reference in accordance with 5 U.S.C. 552(a). The availability of this incorporation by reference is given in paragraph (d)(1) of this section.