



November 2, 2022

Martha E. Marrapese
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Re: Prenotification Consultation PNC 2816

Dear Ms. Marrapese:

This opinion letter is in response to your electronic submission (PNC 2755), received on July 7, 2022, submitted on behalf of Material Difference Technologies, LLC (MDT), requesting the Agency to confirm the MDT's primary recycling process to produce post-industrial recycled polypropylene (PIR-PP) for food contact applications. The PIR-PP is intended for use at levels of up to 100% recycled content in the production of thermoformed, injection-molded, and extruded articles in contact with all food types and Conditions of Use (COU) as authorized in 21 CFR 177.1520 (Olefin polymers).

You submitted a request e-mail, a cover letter and four Appendices. Appendix - A: Process diagram; Appendix - B: Photograph of MDT's Post-Industrial Feed Stock; Appendix - C: Product sheet for Formolene 1102KR from Formosa Plastics; Appendix -D: Safety Data Sheets for additives: ENGAGE™ 8401 Polyolefin Elastomer (1-octene, polymer with ethene, $\geq 99\%$) from Dow (pp. 1-11), and CR20P (80 wt-% of proprietary resin blend and 20 wt-% of di(tert-butylperoxyisopropyl) benzene) from Polyvel Inc.

We reviewed the information provided in this submission for MDT's recycling process, and determined that the feedstock is sourced from PIR-PP scrap that is supplied by Formosa Plastics and confirmed to be food grade complying with FDA requirements for food contact. According to FDA's Recycling Guidance¹, the primary recycling of PIR scrap produced during the manufacture of food contact articles is not expected to pose a hazard to the consumer and is acceptable, provided GMP is followed. *If PIR-PP is sourced from suppliers other than Formosa Plastics, the regulatory status of the PIR-PP should be verified, including specifications and limitations for food contact, to ensure the finished PIR-PP complies with all existing approvals*

We note the proposed primary process resembles a typical secondary recycling process, including multiple separation steps, washing, drying, blending of PIR-PP with two additives, extrusion, and palletization. However, we have questions and concerns on identities, range of

¹ [Guidance for Industry: Use of Recycled Plastics in Food Packaging \(Chemistry Considerations\) | FDA](#)

levels, and technical effects of the two additives. We determined that ENGAGE™ 8401 polyolefin elastomer (1-octene, polymer with ethene (CAS # 26221-73-8) is listed in 21 CFR 177.1520, but we have questions on CR20P. The regulatory status of the proprietary resin blend is unknown and a range of blending levels of both ENGAGE and CR20P should be fully addressed. In addition, we note that di(tert-butyl-peroxyisopropyl) benzene or 2,2'-bis(tert-butylperoxy)diisopropylbenzene (CAS Reg. No. 25155-25-3) is a peroxide vulcanizer used to manufacture the fluorocarbon cured elastomer that is the subject of effective FCN 246.² More importantly, the use of a peroxide suggests that some type of oxidation chemistry is involved in the blending and/or extrusion process.

In conclusion, although we have no questions on the PIR-PP feedstock, we have a few questions and concerns on identities, range of levels, and technical effects of the two additives used in the pre-blending of the proposed process. In particular the regulatory status of the additive CR20P that contains an unknown component, i.e., a proprietary resin blend, and a peroxide vulcanizer. In addition, we request the use levels of two additives in this pre-blending, whether these two additives are used together or separately, and the intended technical effect or chemical reactions from the additives.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Vanee Komolprasert, Ph.D., P.E.
Consumer Safety Officer
Division of Food Contact Substances
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition

² FCN 246,

https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=FCN&id=246&sort=FCN_No&order=DESC&startrow=1&type=basic&search=246



Material Difference Technologies

Committed to Sustainability and Quality

Phoenix Pro Certified PCR-PP

- Post-Consumer recycled plastic material
 - Natural, Black & White Repro Grades
- Certified by AM Testing & Services, an ISO/IEC 17025:2017 laboratory
- PhoenixPro PCR-PP meets requirements of ISO^o 14021:2016
- Association of Plastic Recyclers (APR) PCR Certification Program
- Continuing certification based upon quarterly data submissions to AM Testing laboratory



PureOlene FDA Grade Certified PIR-PP

- Verified FDA PNC Letter
- Food contact articles approved
- Approved up to 100% recycled content
- Approved additives allowed
- Conditions of Use A – J approved

Available Grades Include:

- PureOlene 2020 PIR, Natural
- PureOlene 4010 PIR, Natural
- PureOlene 4020 PIR, Natural
- PureOlene 6020 PIR, Natural
- Your Spec too!



Material Difference Technologies

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Replas ReNew PIR-PP

A wide range of Extruded grades

- Available with Certified recycled content.
- Custom compounding
- Natural & Black colors

Multiple logistics options

- Bulk Truck
- Super Sacks
- Gaylord Box delivery



Bromley ReNew PIR-PP

A wide range of Extruded grades

- Multiple material conversion options
- Custom compounding
- Black, White & Mixed color options

Multiple logistics options

- Bulk Truck
- Super Sacks
- Gaylord Box delivery