



July 29, 2020

Carole Mislin
Head of Product Stewardship

Silke Wischeropp
General Counsel
Site Manager Switzerland

Archroma Management GmbH
Neuhofstrasse 11
4153 Reinach/BL
Switzerland

Dear Ms. Mislin and Mr. Wischeropp:

The purpose of this letter is to acknowledge the receipt of the voluntary commitment made by Archroma Management GmbH, (hereinafter “Archroma”) for the following food contact substance (FCS) “Copolymer of 2-(dimethylamino) ethyl methacrylate with 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate, N-oxide, acetate (CAS Reg. 1440528-04-0),” which is the subject of effective food contact notification (FCN) 1493.

This commitment, as stated in your correspondence¹ of July 17, 2020, states that Archroma will, by December 31, 2023, voluntarily cease introduction into interstate commerce and delivery for introduction into interstate commerce this FCS for any use in food-contact applications that are subject to the jurisdiction of the U. S. Food and Drug Administration (FDA). This commitment also states that Archroma will, as of January 1, 2021, begin to phase-out the introduction into interstate commerce and delivery for introduction into interstate commerce of products containing the FCS authorized by the above-listed FCN for use in food-contact applications in the United States.

Archroma also committed to provide FDA with annual updates for 2021, 2022, and 2023 by January 31st of the following year, on progress towards their phase-out plan, as well as an interim update in 2023, to be provided by July 31st of 2023. Information to be provided will include the annual market volume of these products sold for use in food-contact applications in the United States. Archroma will also provide similar information from 2019 for comparison purposes. Archroma also agreed to provide analytical samples for the food contact substance authorized by the above-referenced FCN to the extent that it is still commercialized so that FDA may monitor the prevalence of these materials in the marketplace. Analytical samples will include the product as sold by Archroma to their downstream customers, and when available, samples of the product applied to paper and/or paperboard, and the food contact substance as applied in a finished food contact article used for food packaging.

¹ Letter from Carole Mislin and Silke Wischeropp (Archroma Management GmbH) to Dennis Keefe (FDA), dated July 17, 2020.

Under Section 409(h)(2)(C) of the Federal Food, Drug, and Cosmetic Act, “the term ‘food contact substance’ means the substance that is the subject of a notification . . . and does not include a similar or identical substance manufactured or prepared by a person other than the manufacturer identified in the notification.” The original notifier for FCN 1493 was Archroma Management GmbH, which is also listed as the manufacturer/supplier for this FCN on the Inventory of Effective Food-Contact Notifications on FDA’s website as of the date of this letter.

The FCS subject to FCN 1493 belongs to a class of compounds termed short-chain per- and poly-fluoroalkyl substances (PFAS) (compounds with extended perfluorinated chains typically 6 carbon atoms in length). Based on information available to FDA after the above-listed FCN became effective, FDA conducted an updated comprehensive review of current information on the safety of certain short-chain PFAS compounds. FDA’s assessment of the available data on these types of compounds has indicated the need to consider factors in addition to those traditionally considered by the Agency at similar exposure levels. These include additional possible toxic endpoints including, but not limited to, effects on pre- and post-natal development, reproductive health and function, and carcinogenicity.²

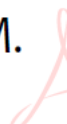
Based on this assessment, FDA informed Archroma that additional testing would be needed to address these safety questions.³ FDA also informed Archroma that the additional testing would need to be of an extended nature to account for the expected body burden levels resulting from chronic exposure to this biopersistent FCS. In response, Archroma discussed with FDA possible plans to voluntarily cease introduction into interstate commerce the FCS from the related FCN for use in food-contact applications sold in the United States, and agreed to a voluntary commitment to cease the introduction and delivery for introduction of the FCS covered by FCN 1493 into interstate commerce for use in any food-contact applications subject to the jurisdiction of the FDA pursuant to the phase-out plan and reporting obligations described above.¹

Archroma has stated that, based upon its prior experience with the usage of such products by companies further down the supply chain, the large majority of existing stocks of the neat FCS, paper and paperboard coated with this FCS, and food packaged in paper coated with this FCS will be exhausted within 18 months of the cessation of initial introduction into interstate commerce. Therefore, it is expected that consumer exposure to this FCS will rapidly decrease, and that little to no additional exposure will occur 18 months after the voluntary phase-out ends.

FDA maintains an Inventory of Effective Food Contact Notifications on FDA’s website.⁴ FDA intends to update this inventory to reflect the commitment by Archroma with respect to this FCN.

Sincerely,

Dennis M.
Keefe -S



Digitally signed by
Dennis M. Keefe -S
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Dennis M. Keefe, Ph.D.
Director
Office of Food Additive Safety

² P. Rice, J. Aungst, J. Cooper, O. Bandele, S. Kabadi, Food and Chemical Toxicology, 2020, 138, 111210.

³ Letter from Dennis Keefe (FDA) to George Misko (Legal Representative for Archroma), dated October 1, 2019.

⁴ “Inventory of Effective Food Contact Substance (FCS) Notifications.” This document can be accessed in the Food Ingredients and Packaging section under the Food topic on the Agency’s internet site at <http://www.fda.gov>.

Center for Food Safety
and Applied Nutrition