

FDA Adds Four New Substances to its Inventory of Effective FCS Notifications 2021

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The U.S. Food and Drug Administration (FDA) recently added four new substances to its [Inventory of Effective Food Contact Substances \(FCS\) Notifications](#). The newly listed substances and the manufacturers are listed below.

The Food and Drug Administration Modernization Act of 1997 amended the Federal Food, Drug, and Cosmetic Act to provide for the submission of food-contact notifications (FCNs). Under the FCN system, a manufacturer or supplier of a food-contact material may submit an FCN to FDA regarding the identity and use of a new food-contact substance (FCS), along with information supporting the conclusion that the substance is safe for the intended use.

If FDA does not object in writing within 120 days to the substance's use based on safety grounds, the submitter and its customers may market the substance. Once the notification becomes effective, FDA will add it to its Inventory of Effective FCS Notifications. For more background on submission of FCNs, please see the PackagingLaw.com article, [What is the Best Approach to Obtaining FDA Clearance for Food Contact Substances?](#)

FCN No.	Food Contact Substance	Manufacturer/Supplier	Effective Date
2119	Tin (IV) oxide (CAS Reg. No. 18282-10-5). REPLACES FCN 431	Merck KGaA, Darmstadt, Germany and its affiliated companies	April 27, 2021
2117	Fluorophlogopite-based pearlescent pigments	Merck KGaA, Darmstadt, Germany and its affiliated companies	April 7, 2021
2013	Acrylic copolymer	The Sherwin-	April 22, 2021

	derived from styrene, butyl methacrylate, acrylic acid, methacrylic acid, and ethyl acrylate	Williams Company	
2110	Reaction product of the three substances: Coconut oil polymer with ethylene glycol, glycerol, and phthalic anhydride (CAS Reg. No. 68413-10-5); 1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)- polymer with bis(isocyanatomethyl)benzene (CAS Reg. No. 51852-81-4); and 1-Propanamine 3-(triethoxysilyl)- (CAS Reg. No. 919-30-2)	DIC Corporation	April 15, 2021

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