



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0403]

Food Contact Notifications That Are No Longer Effective

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing its determination that the Food Contact Notifications (FCNs) listed in this notice are no longer effective. Several manufacturers notified FDA in writing that they ceased producing, supplying, or using the listed food contact substances (FCSs) for their intended use in the United States. We are taking this action in accordance with the process set out in our regulations, by which FDA may determine that an FCN is no longer effective.

DATES: *Applicable date:* This determination for the FCNs listed in table 1 and table 2 is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Compliance date: June 30, 2025, is the compliance date for the FCSs listed in table 2 that were produced, supplied, or used by the manufacturer or supplier prior to the effective date of this determination.

ADDRESSES: For access to the docket to read background documents or comments received go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this document into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lillian Mawby, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301-796-4041 or Carrol Bascus,

Office of Policy, Regulations and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of March 22, 2024 (89 FR 20306), FDA issued a final rule to amend its regulations at § 170.105 (21 CFR 170.105) to provide additional reasons, other than safety, that may form the basis to determine that an FCN is no longer effective. One reason we may determine that an FCN is no longer effective is when the manufacturer or supplier has ceased or will cease the production, supply, or use of the food contact substance for its intended use authorized by the FCN (referred to as “abandonment”).

Several manufacturers or suppliers notified FDA, through voluntary commitment letters (Ref. 1), that they have ceased producing, supplying, or using authorized FCSs for their intended food contact use in the United States. FDA received this information before issuing the final rule. After the final rule’s effective date of May 21, 2024, consistent with § 170.105(a)(2)(ii)(A), we contacted the manufacturers or suppliers to inform them that their voluntary commitment letters demonstrate that they had ceased, and did not intend to resume in the future, producing, supplying, or using the subject FCSs for their intended food contact use. We provided the manufacturers or suppliers an opportunity to respond and did not receive any responses that disagreed with our findings. Therefore, in accordance with § 170.105(a)(2)(ii)(B), we determined that the FCNs are no longer effective based on abandonment. This notice constitutes the detailed summary of the basis for FDA’s determination that these specific FCNs are no longer effective in accordance with § 170.105(b).

Tables 1 and 2 identify FCNs that are no longer effective, as well as the FCSs no longer authorized by these FCNs, as of the publication date of this notice. Based on the end of sales dates provided by the manufacturers for the FCSs listed in FCNs in table 1, we expect any existing stocks of these FCSs to have already been exhausted from the U.S. market. For the

FCSs listed in the FCNs in table 2, we are providing a compliance date for existing stocks of products that were produced, supplied, or used by the manufacturer or supplier before [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Based on the information provided in the voluntary commitment letter from that manufacturer, we expect any existing stocks of these products to be exhausted by June 30, 2025. We have determined that providing a compliance date of June 30, 2025, to exhaust these existing stocks would be protective of public health. For this reason, in accordance with § 170.105(b) we are establishing a compliance date of June 30, 2025, for the use of FCSs listed in table 2 in food contact articles if the FCSs were produced, supplied, or used by the manufacturer or supplier before [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Table 1.--Food Contact Notifications (FCNs) no longer effective as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]

FCN No.	FCS	Manufacturer/Supplier
59	Glycine, N,N-bis[2-hydroxy-3-(2-propenyloxy)propyl]-, monosodium salt, reaction products with ammonium hydroxide and pentafluoroiodoethane-tetrafluoroethylene telomer (CAS Reg. No. 220459-70-1)	BASF Corporation
187	Fluorinated polyurethane anionic resin (CAS Reg. No. 328389-91-9) prepared by reacting perfluoropolyether diol (CAS Reg. No. 88645-29-8), isophorone diisocyanate (CAS Reg. No. 4098-71-9), 2,2-dimethylolpropionic acid (CAS Reg. No. 4767-03-7), and triethylamine (CAS Reg. No. 121-44-8).	Solvay Specialty Polymers Italy S.p.A.
195	Diphosphoric acid, polymers with ethoxylated reduced Me esters of reduced polymerized oxidized tetrafluoroethylene (CAS Reg. No. 200013-65-6). This substance is also known as: phosphate esters of ethoxylated perfluoroether, prepared by reaction of ethoxylated perfluoroether diol (CAS Reg. No. 162492-15-1) with phosphorous pentoxide (CAS Reg. No. 1314-56-3) or pyrophosphoric acid (CAS Reg. No. 2466-09-3).	Solvay Specialty Polymers Italy S.p.A.
206	Copolymer of 2-perfluoroalkylethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, and glycidyl methacrylate	DuPont Chemical Solutions Enterprise
255	3-cyclohexane-1-carboxylic acid, 6-((di-2-propenylamino)carbonyl)-, (1R,6R), reaction products with pentafluoroiodoethane-tetrafluoroethylene telomer, ammonium salts	BASF Corporation
311	Copolymers of 2-perfluoroalkylethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, and glycidyl methacrylate	DuPont Chemical Solutions Enterprise
314	2-Propen-1-ol, reaction products with pentafluoroiodoethane-tetrafluoroethylene telomer, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine (CAS Reg. No. 464178-90-3).	Solenis LLC

338	Copolymers of 2-perfluoroalkylethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, and glycidyl methacrylate.	DuPont Chemical Solutions Enterprise
398	Perfluoropolyether dicarboxylic acid (CAS Reg. No. 69991-62-4), ammonium salt.	Solvay Specialty Polymers Italy S.p.A.
416	Diphosphoric acid, polymers with ethoxylated reduced methyl esters of reduced polymerized oxidized tetrafluoroethylene (CAS Reg. No. 200013-65-6). This substance is also known as phosphate esters of ethoxylated perfluoroether, prepared by reaction of ethoxylated perfluoroether diol (CAS Reg. No. 162492-15-1) with phosphorous pentoxide (CAS Reg. No. 1314-56-3) or pyrophosphoric acid (CAS Reg. No. 2466-09-3).	Solvay Specialty Polymers Italy S.p.A.
487	2-propen-1-ol, reaction products with pentafluoroiodoethane-tetrafluoroethylene telomer, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine (CAS Reg. No. 464178-90-3).	Solenis LLC
518	2-propen-1-ol, reaction products with pentafluoroiodoethane-tetrafluoroethylene telomer, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine (CAS Reg. No. 464178-90-3).	Solenis LLC
538	Perfluoropolyether dicarboxylic acid (CAS Reg. No. 69991-62-4), ammonium salt.	Solvay Specialty Polymers Italy S.p.A.
542	2-propen-1-ol, reaction products with 1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-6-iodohexane, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine (CAS Reg. No. 464178-94-7).	Solenis LLC
628	Copolymer of 2-perfluoroalkylethyl acrylate, 2-(dimethylamino)ethyl methacrylate, and oxidized 2-(dimethylamino)ethyl methacrylate (CAS Reg. No. 479029-28-2).	Clariant Corporation
646	Copolymers of 2-perfluoroalkylethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, glycidyl methacrylate, acrylic acid, and methacrylic acid (CAS Reg. No. 870465-08-0).	Dupont Chemical Solutions Enterprise
746	2-propen-1-ol, reaction products with 1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-6-iodohexane, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine (CAS Reg. No. 464178-94-7) as manufactured in accordance with the description in the FCN.	Solenis LLC
783	2-propen-1-ol, reaction products with 1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-6-iodohexane, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine (CAS Reg. No. 464178-94-7) as manufactured in accordance with the description in the FCN.	Solenis LLC
820	2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester, polymer with α -(1-oxo-2-propen-1-yl)- ω -hydroxypoly(oxy-1,2-ethanediyl).	Daikin America, Inc.
827	2-propenoic acid, 2-hydroxyethyl ester, polymer with α -(1-oxo-2-propen-1-yl)- ω -hydroxypoly(oxy-1,2-ethanediyl), α -(1-oxo-2-propen-1-yl)- ω -[(1-oxo-2-propen-1-yl)oxy]poly(oxy-1,2-ethanediyl) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate (CAS Reg. No. 1012783-70-8).	Daikin America, Inc.
885	2-propenoic acid, 2-methyl-, polymer with 2-(diethylamino)ethyl 2-methyl-2-propenoate, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, acetate (CAS Reg. No. 1071022-26-8)	The Chemours Company FC, LLC

888	2-propenoic acid, 2-hydroxyethyl ester, polymer with α -(1-oxo-2-propen-1-yl)- ω -hydroxypoly(oxy-1,2-ethanediyl), α -(1-oxo-2-propen-1-yl)- ω -[(1-oxo-2-propen-1-yl)oxy]poly(oxy-1,2-ethanediyl) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate (CAS Reg. No. 1012783-70-8).	Daikin America, Inc.
933	2-propenoic acid, 2-methyl-, polymer with 2-hydroxyethyl 2-methyl-2-propenoate, α -(1-oxo-2-propen-1-yl)- ω -hydroxypoly(oxy-1,2-ethanediyl) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate, sodium salt (CAS Reg. No. 1158951-86-0).	Daikin America, Inc.
940	Hexane, 1,6-diisocyanato-, homopolymer, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-1-octanol-blocked (CAS Reg. No. 357624-15-8).	The Chemours Company FC, LLC
962	Diphosphoric acid, polymers with ethoxylated reduced methyl esters of reduced polymerized oxidized tetrafluoroethylene (CAS Reg. No. 200013-65-6). This substance is also known as phosphate esters of ethoxylated perfluoroether, prepared by reaction of ethoxylated perfluoroether diol (CAS Reg. No. 162492-15-1) with phosphorous pentoxide (CAS Reg. No. 1314-56-3) or pyrophosphoric acid (CAS Reg. No. 2466-09-3).	Solvay Specialty Polymers USA, LLC
1027	2-propenoic acid, 2-methyl-, polymer with 2-(diethylamino)ethyl 2-methyl-2-propenoate, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, acetate (CAS Reg. No. 1071022-26-8).	The Chemours Company FC, LLC
1044	2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester polymer with 1-ethylenyl-2-pyrrolidinone, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate sodium salt (CAS Reg. No. 1206450-10-3).	Daikin America, Inc.
1097	Hexane, 1,6-diisocyanato-, homopolymer, α -[1-[[[3-(dimethylamino)propyl]amino]propyl]amino]carbonyl]-1,2,2,2-tetrafluoroethyl]- ω -(1,1,2,2,3,3,3-heptafluoropropoxy)poly[oxy(trifluoro(trifluoromethyl)-1,2-ethanediyl)]-blocked (CAS Reg. No. 1279108-20-1).	Archroma U.S., Inc.
1360	2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymer with 1-ethylenyl-2-pyrrolidinone and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate, acetate (CAS Reg. No. 1334473-84-5).	Daikin America, Inc.
1451	2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymer with 1-ethylenyl-2-pyrrolidinone and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate, acetate (CAS Reg. No. 1334473-84-5).	Daikin America, Inc.
1493	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)	Archroma Management GmbH

Table 2. Food Contact Notifications (FCNs) no longer effective as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER] with a compliance date of June 30, 2025.

FCN No.	FCS	Manufacturer/Supplier
599	Copolymer of perfluorohexylethyl methacrylate, 2-N,N-diethylaminoethyl methacrylate, 2-hydroxyethyl methacrylate, and 2,2'-ethylenedioxydiethyl dimethacrylate, acetic acid salt (CAS Reg. No. 863408-20-2) or malic acid salt (CAS Reg. No. 1225273-44-8).	Asahi Glass Co., Ltd. (Manufacturer) and AGC Chemicals Americas, Incorporated

604	Copolymer of perfluorohexylethyl methacrylate, 2-N,N-diethylaminoethyl methacrylate, 2-hydroxyethyl methacrylate, and 2,2'-ethylenedioxydiethyl dimethacrylate, acetic acid salt (CAS Reg. No. 863408-20-2) or malic acid salt (CAS Reg. No. 1225273-44-8).	Asahi Glass Co., Ltd. (Manufacturer) and AGC Chemicals Americas, Incorporated
1186	Butanedioic acid, 2-methylene-, polymer with 2-hydroxyethyl, 2-methyl-2-propenoate, 2-methyl-2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, sodium salt (CAS Reg. No. 1345817-52-8).	Asahi Glass Co., Ltd. AGC Chemicals Americas, Inc.
1676	2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, polymer with 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, sodium salt (CAS Reg. No. 1878204-24-0).	Asahi Glass Co., Ltd. AGC Chemicals Americas, Inc.

To reflect these changes in status of the affected FCNs, we established an Inventory of Food Contact Notifications That are No Longer Effective on FDA's website. The Inventory may be viewed at <https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=FCN-no-longer-effective>.

We also updated our Inventory of Effective Food Contact Notifications accordingly at <https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=FCN>.

A food additive is deemed unsafe unless that substance and its use conform with a regulation issued under section 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348) or there is an FCN submitted under section 409(h) of the FD&C Act that is effective (section 409(a) of the FD&C Act). An effective FCN is specific only to the intended use of the substance prepared by the manufacturer or supplier identified in the FCN (section 409(h)(1)(C)).

Our determination that an FCN is no longer effective does not preclude any manufacturers or suppliers from submitting a new FCN for the same FCS, including for the same intended use, after FDA has determined that an FCN is no longer effective, unless the intended use of the FCS is authorized by a food additive regulation or the subject of an issued threshold of regulation exemption, per 21 CFR 170.105(c).

II. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(m) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. References

The following references are on display at the Dockets Management Staff, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, RM. 1061, Rockville, MD 20852, 240-402-7500 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. Although FDA has verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA, Market Phase-Out of Grease-Proofing Substances Containing PFAS, Commitment Letters from Industry available at: <https://www.fda.gov/food/process-contaminants-food/market-phase-out-grease-proofing-substances-containing-pfas>.

Dated: December 30, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024-31692 Filed: 1/3/2025 8:45 am; Publication Date: 1/6/2025]