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Threshold of Regulation (TOR) Exemptions

Last updated April 2024

Listed below are the exemptions that have been issued under 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles*. Threshold of Regulation Exemptions are generally applicable and are effective for the food contact substance (FCS) for the listed intended use regardless of manufacturer or supplier. The list includes the name of the company that made the request, the chemical name of the substance, the specific use for which the substance received an exemption from regulation as a food additive, and any appropriate limitations on the substance's use. Questions pertaining to this list should be directed to the Office of Food Additive Safety (premarket@fda.hhs.gov).

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File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
2023-001	IHI Ionbond AG and its affiliates	Chromium-tungsten carbide-amorphous hydrogenated carbon alloy with a sublayer of chromium	For use as a coating, or a component of coatings, including multilayer coatings, on repeated-use metal food-contact articles, including on parts in food processing and food packaging machinery and equipment to reduce surface wear, friction, and sticking of food to materials. The FCS is not for use in contact with infant formula or human milk.
2022-002	Superior Glove	Tungsten (CAS Reg. No. 7440-33-7)	For use as a component of protective gloves intended for repeated use in contact with all types of food at temperatures ranging from 0-40°C (32-104°F). The food contact substance (FCS) is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the TOR exemption.

File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
2022-001	IHI Ionbond AG and its affiliates	Zirconium nitride and zirconium carbon nitride	For use as a ceramic coating, or a component of ceramic coatings, including multilayer coatings, on repeated-use component parts in food processing and food packaging machinery and equipment. The FCS is not for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of the substance in the TOR exemption.
2021-006	Aquaporin A/S	A cross-linked polyamide (complying with 21 CFR 177.2550) modified with proteopolymersomes assembled with Aquaporin Z, aminopropyl-terminated polydimethylsiloxane, and polydimethylsiloxane-polymethyloxazoline copolymers	For use as a component of reverse osmosis membranes otherwise complying with 21 CFR 177.2550. The FCS may be used in repeat-use filtration membranes in contact with all food types at temperatures up to 50°C (122°F). The FCS is not intended for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the TOR exemption.
2021-005	Taiyo Yuden Chemical Technology Co. Ltd.	Silicon-doped diamond-like carbon	For use as a coating on repeated-use food processing equipment to reduce the coefficient of friction of food processing equipment. The thickness of the coating will not exceed 1 µm. The food contact substance (FCS) is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the TOR exemption.
2021-004	IHI Ionbond AG and its affiliates	Chromium coated with a layer of tungsten carbide-chromium and a subsequent layer of tungsten carbide-amorphous hydrogenated carbon	For use as a coating on repeated-use metal component parts in food processing and packaging machinery and equipment to reduce surface wear, friction, and adhesion to food, except for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the TOR exemption.
2021-003	FDA	Metal carbides and metal carbide alloys, including: tungsten carbide with or without nickel, cobalt, chromium, iron, boron, silicon, or aluminum; molybdenum carbide; silicon carbide; titanium carbide; chromium carbide; tantalum carbide; niobium carbide; and vanadium carbide	As a component or ceramic coating in repeat-use applications such as parts in food processing equipment (e.g., wear parts such as nozzles, bearings, seal rings, pumps, etc.) and in saws, cutting tools, and other uses where these substances are used as a durable, abrasion- and corrosion-resistant coating. The FCS will be used in contact with all types of foods and under Conditions of Use A through H as described in Table 1. The FCS is not intended to be used in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the TOR exemption.
2021-002	CHEP USA	D&C Orange No. 4 (CAS Reg. No. 633-96-5)	For use as a colorant in a coating used on wooden pallets for hydrocooling produce. Pallets containing the food contact substance may be in contact with water used for hydrocooling produce.
2021-001	IHI Ionbond AG and its affiliates	Amorphous hydrogenated carbon alloy, manufactured by plasma activated chemical vapor deposition using acetylene gas,	As a ceramic coating, or a component of ceramic coatings, including multilayer coatings, on repeated-use component parts in food processing and food

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		optionally with a sublayer comprised of hydrogenated amorphous silicon-carbide alloy	packaging machinery and equipment to reduce surface wear, friction, and sticking of food to materials. The FCS is not for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of the substance in the TOR exemption.
2020-006	Keller and Heckman LLP, on behalf of Elkem Silicones France SAS	Silicic acid, sodium salt, reaction product with chlorotrimethylsilane and isopropyl alcohol (CAS Reg. No.: 68988-56-7)	For use as a component of wet-end defoamers used in the manufacture of food-contact paper and paperboard at levels of up to 58.5 parts per million (ppm) relative to pulp solids. The food contact substance (FCS) is not intended for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of the substance in the TOR submission.
2020-005	DHI A/S on behalf of Aquaporin A/S	A cross-linked polyamide (complying with 21 CFR 177.2550) modified with proteopolymersomes assembled with Aquaporin Z (AqPZ), aminopropyl-terminated polydimethylsiloxane, and polydimethylsiloxane-polymethyloxazoline copolymers	As a component of osmosis membranes and reverse osmosis membranes otherwise complying with 21 CFR 177.2550. The FCS may be used in repeat-use filtration membranes in contact with all food types at temperatures up to 40°C (104 °F). The FCS is not intended for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the TOR exemption.
2020-004	IHI Ionbond AG and its affiliates	Chromium nitride	The FCS is intended for use as a ceramic coating, or a component of ceramic coatings, including multilayer coatings, on repeated-use food-contact articles. The FCS is not for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of the substance in the TOR exemption.
2020-003	IHI Ionbond AG and its affiliates	Titanium Nitride (CAS Reg. No. 25583-20-4)	For use as a ceramic coating, or a component of ceramic coatings, including multilayer coatings, on repeated-use metal component parts in food processing and food packaging machinery and equipment to reduce surface wear, friction, and sticking of food to materials. The FCS is not for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of the substance in the TOR exemption.
2020-002	Kaneka Belgium NV	2,4-dimethyl-6-(1-methylpentadecyl)phenol (CAS Reg. No. 134701-20-5)	As an antioxidant/stabilizer at levels not to exceed 0.3 percent weight of 2-propenoic acid, 2-methyl-, 1-methyl-1,3-propanediyl ester, polymer with 1,3-butadiene, butyl 2-propenoate, ethenylbenzene, and methyl 2-methyl-2-propenoate (CAS Reg. No. 143646-08-6 or 25101-28-4). The FCS is intended to be used in repeat-use articles in contact with aqueous, acidic, low alcoholic (<20% alcohol) and dry foods, and at a maximum temperature of 40 °C. The FCS is not for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of the

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2020-001	Kaneka Belgium NV	octadecyl 3,5-di-tert-butyl-4-hydroxyhydrocinnamate (CAS Reg. No. 2082-79-3)	As an antioxidant/stabilizer at levels not to exceed 0.08 percent weight of 2-propenoic acid, 2-methyl-, 1-methyl-1,3-propanediyl ester, polymer with 1,3-butadiene, butyl 2-propenoate, ethenylbenzene, and methyl 2-methyl-2-propenoate (CAS Reg. No. 143646-08-6 or 25101-28-4). The FCS is intended to be used in repeat-use articles in contact with aqueous, acidic, low alcoholic (<20% alcohol), and dry foods, and at a maximum temperature of 40 °C. The FCS is not for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of the substance in the TOR exemption request.
2019-001	FABES Forschungs-GmbH, on behalf of Albert Handtmann Elteka GmbH & Co. KG.	Polyamide 12 material (CAS Reg. No. 24937-16-4)	For use as a component of repeat-use food-contact articles intended to contact all foods at temperatures not to exceed 90°C. The food contact substance (FCS) is not intended for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of the substance in the TOR submission.
2018-002	NSF International, on behalf of Trelleborg Sealing Solutions Americas	Carbon fiber (CAS Reg. No. 308063-56-1), produced from pitch precursors (i.e., pitch-based carbon fiber)	For use as filler in polytetrafluoroethylene (PTFE) seals for repeated use in contact with all food types at a use level not to exceed 11% by weight of the finished seal. The food contact substance (FCS) is not for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of the substance in the TOR submission.
2018-001	Schunk Kohlenstofftechnik GmbH	pyrolytic carbon (PyC)	For use as a coating on burst discs used in food processing equipment. The thickness of the PyC coating will not exceed 25 µm. The food contact substance (FCS) is not for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of the substance in the TOR exemption.
2017-004	Gradient on behalf of Parker Hannifin Corporation	1-propanone, 2-hydroxy-1-(4-(2-hydroxyethoxy)phenyl)-2-methyl- (CAS Reg. No. 106797-53-9) and 2-propenamide, N,N-methylenebis- (CAS Reg. No. 110-26-9)	1-propanone, 2-hydroxy-1-(4-(2-hydroxyethoxy)phenyl)-2-methyl- (CAS Reg. No. 106797-53-9) may be used as a photoinitiator in the manufacture of polyether sulfone (PES) filter membranes. 2-propenamide, N,N-methylenebis- (CAS Reg. No. 110-26-9) may be used as a hydrophilic crosslinker in the manufacture of PES filter membranes. The PES filter membranes may be used for filtration of aqueous, acidic, and alcoholic (50% alcohol or less) foods, except for infant formula and human milk, at room temperature or below. The PES filter membranes are for repeat use and can be sterilized between uses at temperatures up to 130°C for two hours. PES filter membranes containing the subject food contact substances are

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2017-003	NSF International, on behalf of Ace Chemical Products, Inc.	A mixture of fluorescein sodium (CAS Reg. No. 518-47-8), C ₆₋₁₂ alkyl alcohol ethoxylate phosphoric acid (CAS Reg. No. 68921-24-4), C ₈₋₁₀ alkyl alcohol ethoxylate phosphoric acid (CAS Reg. No. 68130-47-2), and benzenesulfonic acid, 4-C ₁₀₋₁₃ -sec-alkyl derivatives (CAS Reg. No. 85536-14-7)	not for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of these substances in the TOR exemption.
2017-002	GRAS Associates, LLC on behalf of REMA TIP TOP/North America, Inc.	Isocyanic acid, polymethylenopolyphenylene ester (PMDI) (CAS Registry Number 9016-87-9)	As a lubricant for use in the conveyance of beverage containers at a combined total level not to exceed 0.8 weight % in dispersions applied to the conveyor belt below the bottle opening. The FCS is not intended for use in the conveyance of beverage bottles intended for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of these substances in the TOR submission.
2017-001	GRAS Associates, LLC on behalf of REMA TIP TOP/North America, Inc.	4,4'-diphenylmethane diisocyanate (MDI)(CAS Reg. No. 101-68-8)	For use as a cross-linker for adhesives used in repeat use articles under the use conditions specified by 21 CFR 175.105(a)(2). The FCS is not intended for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of these substances in the TOR submission.
2016-004	GRAS Associates, LLC on behalf of REMA TIP TOP/North America, Inc.	tris(4-isocyanatophenyl) thiophosphate (CAS Reg. No. 4151-51-3)	For use as a cross linking agent in copolymers used as adhesives in repeated use applications under the use conditions specified by 21 CFR 175.105(a)(2). The FCS is not for use in contact with infant formula or human milk. Such uses were not included as part of the intended use of the substance in the TOR submission.
2016-003	Taghleef Industries LLC	Propylene glycol mono- and diesters of fatty acids regulated in 21 CFR 172.856	For use as an antistatic and/or antifogging agent at levels not to exceed 1.0 percent by weight of polypropylene films regulated in 21 CFR §177.1520 and having a maximum thickness of 40 micrometers in contact with all food types except infant formula and breast milk. Use in contact with infant formula and breast milk was not included as part of the intended use of the substance in the TOR exemption request.
2016-002	Freudenberg Sealing Technologies GmbH & Co. KG	carbon black (CAS Reg. No. 1333-86-4) produced by furnace combustion	For use at levels up to 50% by weight of rubber articles complying with 21 CFR 177.2600 (Rubber articles intended for repeat use). Rubber articles containing the FCS may contact milk and edible oils, except for infant formula and breast milk. Use in contact with infant formula and breast milk was not included as part of the intended use of the substance in the TOR submission.

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2016-001	NSF International on behalf of CarboLine Company	hexamethylenediamine (CAS Reg. No. 124-09-4), 1,2-diaminocyclohexane (CAS Reg. No. 694-83-7), and 4,4-methylenebis(2-ethylbenzamine) (CAS Reg. No. 19900-65-3)	For use as curing agents in epoxy resins complying with 21 CFR 175.300(b)(3)(viii). The final coating will be used on the food contact surface of repeat use bulk food containers (i.e., railcars, ship holds, tanker trailers, etc.) only, in contact with all foods under conditions of use C through G (including hot-fill applications above 66°C (150°F)). The final coating should meet the extractives specifications in §175.300(c) and be thoroughly cleansed prior to its first use in contact with food in accordance with §175.300(g).
2015-003	ChemCal, Inc.	sodium fluorescein (CAS Reg. No. 518-47-8)	For use as an inert tracer chemical for use in boiler water additives complying with 21 CFR 173.310. The food contact substance (FCS) will be used at a maximum use level 500 parts per billion in the boiler water and must meet any applicable specifications under 21 CFR 173.310. The FCS is not for use in boiler water systems involved in the processing of infant formula or its ingredients. Such use was not included as part of the intended use of the substance in the TOR submission.
2015-002	Keller and Heckman, LLP on behalf of Eastman Chemical Company	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate (CAS Reg. No. 2082-79-3)	For use as an antioxidant/stabilizer at a maximum use level of 0.3% by weight of the polymer in polymers of dimethyl terephthalate, 1,4-cyclohexanediethanol, and 2,2,4,4-tetramethyl-1,3-cyclobutanediol (CAS Reg. No. 261716-94-3) containing repeat units consisting of terephthalate esters of 2,2,4,4-tetramethyl-1,3-cyclobutanediol at up to 40 mole percent (expressed as mole percent of the glycol component of the finished polyesters) and 1,4-cyclohexanediethanol at no less than 60 mole percent, and, optionally, ?0.5 percent (by weight of the finished resin) trimellitic anhydride (CAS Reg. No. 552-30-7) as a branching agent. Food contact articles made with the subject additive are intended only for repeated use in contact with all food types (except infant formula and breast milk) at temperatures up to and including 100°C. Use in contact with infant formula and breast milk was not included as part of the intended use of the substance in the TOR submission.
2015-001	Intertek Wilton	1-propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-C12-18 acyl derivs., C12-18-alkyl esters, chlorides (CAS Reg. No. 71486-89-0)	For use as a slip agent in acrylic and modified acrylic polymers complying with 21 CFR 177.1010. The food contact substance (FCS) will be used at a maximum use level of 0.1% in the finished polymer. The finished polymer will be used in contact with all foods at room temperature and below in repeat-use applications only. The finished polymer should be thoroughly cleansed prior to its first use in contact with food in accordance with §177.1010(d).
2014-003	REPLACED BY _____	_____	_____

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	TOR 2016-001 ⁹		
2014-002	Keller and Heckman, LLP on behalf of Whitford Corporation	Methyltrimethoxysilane (CAS Reg. No. 1185-55-3) and methyltriethoxysilane (CAS Reg. No. 2031-67-6)	For use as monomers in silicone resins complying with 21 CFR 175.300(b)(3) (xxviii). The finished resin will be used in repeat use food contact applications only and should meet the extractives specifications in §175.300(c) and be thoroughly cleansed prior to its first use in contact with food in accordance with §175.300(g).
2014-001	Interplastic Corporation	4-hydroxy-2,2,6,6-tetramethylpiperidinoxy (CAS Reg. No. 2226-96-2)	For use as an inhibitor in the polymerization of thermosetting styrenated polyester resins complying with 21 CFR 177.2420. The food contact substance (FCS) may be used at a level not to exceed 0.08 % by weight of the finished resin. If used with other inhibitors allowed for use in resins complying with 21 CFR 177.2420, the total combined use level of all inhibitors cannot exceed 0.08 % by weight of the finished resin. The finished resin is intended for use as articles or components of articles for repeated use in contact with food, provided the finished resins meet the extractive limitations in 21 CFR 177.2420(c) and the finished articles are thoroughly cleansed prior to their first use in contact with food in accordance with 21 CFR 177.2420(d).
2013-001	BIOSAFE, Inc.	A mixture of 3-(trihydroxysilyl)propyltrimethyloctadecyl ammonium chlorides (CAS Reg. No. 199111-50-7)	For use as an antimicrobial to preserve finished food contact articles. The food contact substance (FCS) will be used as an additive without food type or temperature limitation in: <ol style="list-style-type: none"> 1. food preparation surfaces (where the FCS is either incorporated into the resin, a food contact laminate layer, or applied to the surface as part of a coating). The FCS may be used at a maximum use level of 1 weight percent of the resin, laminate, or coating. 2. polymeric tubing for the transfer of beverages. The FCS may be used at a maximum use level of 1 weight percent of the finished tubing. 3. repeat use activated carbon water filters. The FCS may be used at a maximum use level of 0.25 weight percent of the carbon block.
2012-002	Mizuawa Industrial Chemicals, Ltd	Sodium calcium aluminosilicate particles surface modified with up to 0.5 weight percent of 3-(triethoxysilyl) propylamine	For use as an anti-blocking additive in Nylon films, up to a level of 1000 ppm (0.1 weight percent) of the finished film. The finished film will have a maximum thickness of 25 µm and will be used in contact with all foods in applications up to 121°C.
2012-001	Ecolab	A mixture of 1,3-propanediamine, N-9-octadecenyl-, (Z)- (CAS Reg. No. 7173-62-8), amines, N-coco alkyltrimethylenedi- (CAS Reg. No. 61791-63-7), cocamine (CAS Reg. No. 61788-46-3), poly(oxy-1,2-ethanediyl), α-isotridecyl-ω-hydroxy- (CAS Reg. No. 9043-30-5), poly(oxy-1,2-ethanediyl), α-tridecyl-ω-hydroxy-, branched (CAS Reg. No 69011-36-5),	For use as a lubricant for use in the conveyance of beverage containers. The subjects of the TOR request can be used at a combined total level not to exceed 0.75 weight % in dispersions applied to the conveyor belt below the bottle opening.

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2011-002	Keller and Heckman, LLP.	poly(oxy-1,2-ethanediyl), α -(carboxymethyl)- ω [(9Z)-9-octadecen-1-yloxy]- (CAS Reg. No. 57635-48-0), and potassium acetate (CAS Reg. No 127-08-2)	Polyethylene glycol with a minimum molecular weight of 400 Daltons (CAS Reg. No. 25322-68-3)	For use as a modifier for polyethylene terephthalate films with a maximum thickness of 2 mils. The subject of the TOR request may be used at a level not to exceed 12 % by weight of the final film. The resulting finished article may be used in contact with all food types (or according to other applicable limitations/specifications as appropriate) under Conditions of Use E through G.
2011-001	Nanobiomatters BactiBlock S.L.	Silver (CAS Reg. No. 7440-22-4) and cetyltrimethylammonium bromide (CAS Reg. No. 57-09-0)	Silver (CAS Reg. No. 7440-22-4) and cetyltrimethylammonium bromide (CAS Reg. No. 57-09-0)	For use as components of an antimicrobial formulation to be used to preserve composite countertops consisting of a polymeric binder and inorganic filler. The antimicrobial formulation will contain up to 0.5 % by weight of silver and up to 30 % by weight of cetyl trimethylammonium bromide with the remainder consisting of a suitable substance regulated for the intended use. The antimicrobial formulation will be incorporated into the polymeric binder at a level not to exceed 1 % by weight. The final composite countertop will incorporate the polymeric binder at a level not to exceed 10 % by weight with the remainder consisting of inorganic filler of a quality suitable for food-contact use. The final food contact article will be used in contact with all foods at room temperature and below.
2010-003	Engineered nanoProducts Germany AG	Vitreous silica coating prepared by sol-gel polycondensation reaction of tetraethoxysilane and methyl-triethoxysilane	Vitreous silica coating prepared by sol-gel polycondensation reaction of tetraethoxysilane and methyl-triethoxysilane	For use as a permanent or semi-permanent coating of metal substrates intended for cooking food in repeat-use applications. The final food contact article will be used in repeat-use cooking applications in contact with all food types at a maximum temperature of 300°C.
2010-002	Sadex, Inc.	The food additives listed in: (a) Title 21 CFR Parts 174 through 186, (b) the inventory of effective food-contact substance notifications, and (c) the inventory of Threshold of Regulation exemptions issued under Title 21 CFR 170.39.	In the manufacture of food-contact articles that will be irradiated, incidental to the radiation processing of prepackaged foods. This exemption applies only when: <ol style="list-style-type: none"> 1. The radiation processing is done in compliance with Title 21 CFR Part 179; 2. The packaging materials are subjected to radiation doses not exceeding 4.5 kGy; 3. The packaged food is irradiated either in a verifiably oxygen-free environment or while frozen and contained under vacuum. 	
2010-001	Tronox, LLC	1,1,1-trimethylolpropane (CAS Reg. No. 77-99-6) and zirconium dioxide (CAS Reg. No. 1314-23-4)	For use as modifying agents for titanium dioxide pigments. Each subject of the TOR request would be used at a maximum level of 0.7% of the titanium dioxide pigment formulation. The resulting titanium dioxide pigment would be used at a level not to exceed 5% by weight of finished repeat-use polymers	

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2009-003	Hitachi Chemical Company, Ltd.	Triethylamine (CAS No. 121-44-8)	For use in the manufacture of polyamide-imide resin intended for use as a component in primer coatings between the metal surface and the fluorocarbon layer of non-stick surfaces of cooking utensils. The final food contact article will be used in repeat-use cooking applications in contact with all food types at a maximum temperature of 290°C.
2009-002	Korea Engineering Plastics Co., Ltd.	Dimethoxymethane (Methylal) (CAS Number: 109-87-5)	For use as a chain transfer agent in the polymerization of polyoxymethylene copolymers in the manufacture of repeat use food-contact articles, at temperatures below 250°F, and in contact with all food types, except those containing more than 15% alcohol.
2009-001	Eric F. Greenberg, P.C. on behalf of Wacker Chemical Corporation	Polysiloxane (dimethyl, 3-hydroxypropyl methyl), ethoxylated propoxylated, polymer with hexamethylenediisocyanate, which is the reaction product resulting from a mixture of two polymeric starting materials with hexamethylenediisocyanate.	The FCS shall be added to the pulp water at a level not to exceed 4 mg/kg of pulp. The food contact substance will act as an antifoaming agent in the production of food contact paper that will contact all types of food.
2008-001	H.B. Fuller	Polyurethane (PUR) resin (CAS Reg. No. 82602-41-3)	For use as an adhesive between layers in the fabrication of laminate food-contact articles used for microwave cooking at temperatures not to exceed 212°F, in contact with aqueous food (food type I, Table 1, 21 CFR 176.170(c).)
2007-006	Kraska Consultants, Inc on behalf of Omnova Solutions,	1,1'-Oxybisbenzene tetrapropylene derivatives, sulfonated, sodium salts (CAS Reg. No. 119345-04-9)	For use as components of adhesives under use conditions as specified in 21 CFR 175.105(a)(2)(i)(ii) and in pressure sensitive adhesives as specified in 21 CFR 175.125(b) on labels and tape applied to raw fruits and raw vegetables. The temperature of use should not exceed 120°F.
2007-005	Ciba Specialty Chemicals Corporation	Tin oxide (SnO ₂), (CAS Reg. No. 18282-10-5),	For use at a maximum concentration of 2.0% by weight as a component in mica-based mineral colorants, provided the maximum loading level for the mica-based colorants in the food-contact article does not exceed 3% by weight for polymers, 5% for paper and paperboard, 15% for coatings or 30% for ink formulations, in contact with all food types and under temperature conditions of use A through H.
2007-004	Kraska Consultants, Inc on behalf of Omnova Solutions	1. 3(2H)-Isothiazolon-3-one, 2-methyl- (CAS Reg. No. 2682-20-4), and 2. 3(2H)-Isothiazolon-3-one, 5-chloro-2-methyl- (CAS Reg. No. 26172-55-4)	Used as components of pressure sensitive adhesives. These substances are used as a biocide preservative according to their FIFRA registrations as product preservatives in water based adhesive products. Also, the adhesive shall be used at GMP levels (i.e., the minimum amount needed to accomplish the intended technical effect) and the use of these biocides in the adhesive formulation shall be 1 percent or less by weight. These substances shall be used in formulations with modified butadiene/styrene copolymers.

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2007-003	Keller and Heckman on behalf of Owens-Illinois Closure Inc.	Hydrogen peroxide (CAS Reg. No. 7722-84-1)	To sterilize food-contact surfaces that have an appropriate regulatory status for its intended use in the production of aseptic packaging and meet the requirements and limitations of 21 CFR 178.1005 <i>Hydrogen peroxide</i> .
2007-002	REPLACED BY TOR 2010-002 ¹⁰	_____	_____
2007-001	Kraska Consultants, Inc.	1. 1,2-Benzisothiazolin-3-one (BIT); (CAS Reg. No. 2634-33-5), 2. 1,1,3-tris(5-tert-butyl-4-hydroxy-2-methylphenyl)butane; (CAS Reg. No. 1843-03-4), and 3. naphthalene sulfonic acid-formaldehyde condensate, sodium salt; CAS Reg. No. 9084-06-4).	As components of an adhesive formulation when used as specified below: Substance A, a biocide preservative will be used according to its FIFRA registration as a product preservative in water based adhesive products. Substances B and C will be used as antioxidants in adhesives and will be used at levels not to exceed 1 percent of the adhesive. The adhesive shall be used at GMP levels (i.e., the minimum amount needed to accomplish the intended technical effect). Also, these substances are limited to use in formulations with modified butadiene/styrene copolymers.
2006-002	Cryovac Sealed Air Corp.	1. Glycerol monooleate complying with 21 CFR 184.1323, as long as it is used at GMP levels (i.e., the minimum amount necessary to achieve the intended effect); 2. Polyamide 6/66 complying with 177.1500(b) 4.2 and 177.1395; and, 3. Polyamide 6/12 complying with 177.1500(b) 13.1 and 177.1395.	Use as a lidding film to cover a polystyrene foam tray intended to be used in contact with ground beef during electron beam irradiation of the ground beef in a nitrogen atmosphere, at doses of 1.5 to 3.0 kGy. This exemption applies when these components are irradiated, incidental to the irradiation processing of prepackaged food, in a vacuum or in an oxygen-free environment at doses not exceeding 3.0 kGy
2006-001	General Electric	Phenol, 4-methyl, reaction products with dicyclopentadiene and isobutylene (CAS Reg. No. 68610-51-5)	As an antioxidant/stabilizer to inhibit thermo-oxidative degradation, in methyl methacrylate modified acrylonitrile/butadiene/styrene (ABS) polymers which are the subject of FCN 190 and acrylonitrile/styrene copolymers complying with 21 CFR 177.1040 and 21 CFR 181.32, at a maximum concentration of 1% by weight, and in contact with food types I, II, IV-B, VI-A, VI-B, VII-B, and VIII under conditions of use C through G, as described in Table 2, 21 CFR 176.170(c).
2005-008	Omaha Steaks Co.	A multilayer packaging film containing: 1. The following substances as long as they meet the applicable use level limitations in §178.2010 or §178.3860 or an effective notification: 1. 1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene (CAS Reg. No. 1709-70-2). 2. Erucamide (CAS Reg. No. 112-84-5) 2. Zinc oxide as long as it is used at GMP levels (i.e. the minimum amount necessary to achieve the intended technical effect); 3. An ionomeric resin, complying with §177.1330, as a component of the food contact layer of the laminate.	The packaging materials are to be used in contact with ground beef during irradiation of the vacuum packed and frozen ground beef at doses not to exceed 3.0 kiloGrays (kGy)

File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
2005-007	Mitec Advanced Technology	<p>4. Polybutylene, complying with §177.1570, as a component of the food contact layer of the laminate.</p> <p>5. An urethane adhesive, provided it complies with §175.105, as a component of the adhesive, non-food contact layer of the laminate.</p> <p>Polystyrene foam tray with a multi-layer food-contact coating. The coating may contain:</p> <ol style="list-style-type: none"> 1. The following substances as long as they meet the applicable use level limitations in §178.2010 or an effective notification: <ol style="list-style-type: none"> 1. Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)methane] (CAS Reg. No. 6683-19-8). 2. Octadecyl 3,5-di-tert-butyl-4-hydroxyhydrocinnamate (CAS Reg. No. 2082-79-3). 3. Di-tert-butylphenyl phosphonite condensation product with biphenyl (CAS Reg. No. 119345-01-6). 4. Tri(mixed mono- and di-nonylphenyl) phosphate (CAS Reg. No. 26523-78-4) 5. Tris(2,4-di-tert-butylphenyl)phosphite (CAS Reg. No. 31570-04-4) 6. Cyclic neopantanetetrayl bis(octadecyl phosphite) (CAS Reg. No. 3806-34-6) 2. The following substances as long as they are used at GMP levels (i.e. the minimum amount necessary to achieve the intended technical effect). <ol style="list-style-type: none"> 1. Butylated hydroxytoluene (BHT) 2. Diatomaceous silica 3. A blend of a styrene-butadiene thermoplastic elastomer and a styrene-butadiene copolymer, both complying with §177.1640, as components of the non-food contact layers of the laminate. 4. An ethylene vinyl alcohol copolymer, complying with §177.1360, as a component of the non-food contact layers of the laminate. 	For use in contact with ground beef during electron beam irradiation of the ground beef in a nitrogen atmosphere, at doses not to exceed 3.0 kilograys (kGy).
2005-006	Ciba Specialty Chemical Corp.	Sodium perchlorate monohydrate (CAS Reg. No. 7791-07-3)	As a conductivity enhancer in the manufacture of antistatic agents for use in polymeric finished articles. The food contact substance may be used at a level not to exceed 1.2 percent by weight of the finished polymer. The finished article may be used in contact with Food Type VIII only.
2005-005	Keller and Heckman on behalf of Dyneon LLC	Polytetrafluoroethylene micropowders	For repeated use applications in contact with all food types under all conditions of use.
2005-004	Keller and Heckman on behalf of Koch Membrane Systems, Inc	A blend of vinyl chloride/vinyl acetate resin, carbon black and isophorone, with maximum use levels of 30%, 20%, and 70%, respectively.	As a black ink formulation to mark the outer membrane of a repeat-use food processing module at levels not to exceed 36 mg.
2005-003	Ciba Specialty Chemical Corp.	Polyvinylpyrrolidone CAS Reg. No.9003-39-8	As a dispersing agent in colorants for all polymers intended for use as components of food-contact articles, at levels not to exceed 0.03 percent by weight of the polymer, and in contact with all food types.

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2005-002	Schiff & Company on behalf of USR Optonix, Inc	Zinc sulfide doped with manganese and copper	Use of manganese at levels up to 0.5 % by weight; and use of copper at levels up to 1.0% by weight and manganese at levels up to 1% by weight as dopants in zinc sulfide pigments used at levels up to 10% by weight in plastic cups, plates and disposable cutlery destined for food-contact applications.
2005-001	Asahi Glass Fluoropolymers, Ltd	Cupric oxide (Cu), copper powder, and aluminum oxide (Al ₂ O ₃)	As thermal stabilizers in the manufacture of ethylene tetrafluoroethylene (ETFE). The maximum use level of the cupric oxide, copper powder, and aluminum oxide (Al ₂ O ₃) in the copolymer shall not exceed 55 ppm, 300 ppm, and 500 ppm, respectively.
2004-003	HP Polymers, Inc	1H,3H-benzo[1,2-c:4,5-c']difuran-1,3,5,7-tetrone, polymer with 5,5'-carbonylbis[1,3-isobenzofuranedione] and 1,3-diisocyanatomethylbenzene (CAS Reg. No. 134119-41-8)	As a filler at a maximum use level of 20% by weight in polytetrafluoroethylene seals, bushings and bearings in food-processing equipment intended for repeated use provided the temperature does not exceed 100E C. In accordance with good manufacturing practice, those food-contact articles containing the subject additive should be thoroughly cleansed prior to their first use in contact with food.
2004-002	Huntsman Corp.	C16 - C18 fatty alcohol reacted with approximately 16 moles of ethylene oxide (natural fatty alcohol) and diethylene glycol monobutyl ether	As a production aid in the manufacture of latex rubber gloves for food contact use complying with 21 FR 177.2600.
2004-001	Interplastic Corp.	2,4-pentanedione (CAS Reg. No. 123-54-6) and N,N-dimethylacetamide (CAS Reg. No. 2044-64-6)	For use at maximum levels of 0.05 percent and 0.08 percent by weight, respectively, to assist the curing of thermosetting styrenated polyester resins complying with 21 CFR 177.2420 and intended for repeat use as articles or as components of articles used in contact with food, the finished resins must meet the extractive limitations in 21 CFR 177.2420(c) and must be thoroughly cleansed prior to their use with food as specified in 21 CFR 177.2420(d).
2003-001	Keller and Heckman	A mixture of parafinic oil (CAS Reg. No. 64742-65-0) and sulfonated paraffinic oil (CAS Reg. No. 64742-20-2)	As components of a grease lubricant with incidental food contact as specified in 21 CFR 178.3570 and at a maximum total use level of 13.2 percent by weight.
2000-003	Keller and Heckman on behalf of BASF Corporation	An ethoxylated and propoxylated tallow fatty alcohol (CAS Reg. No. 68002-96-0)	As a defoaming agent in the manufacture of uncoated paper and paperboard at levels not exceeding 0.1% by weight of dry pulp.
2000-002	HP Polymer, Inc.	1H,3H-benzo(1,2-c:4,5-c')difuran-1,3,5,7-tetrone, polymer with 5,5'-carbonylbis(1,3-isobenzofuranedione) and 1,3-diisocyanatomethylbenzene	As a filler at a maximum use level of 20% by weight in polytetrafluoroethylene seals, bushings and bearings in food-processing equipment intended for repeated use provided the temperature does not exceed 120°F. In accordance with good manufacturing practice, those food-contact articles containing the subject additive should be thoroughly cleansed prior to their first use in contact with food.

File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
2000-001	Keller and Heckman on behalf of KoSa	Polyethylene terephthalate/isophthalate copolymers containing 94 weight percent of the polymer units derived from ethylene terephthalate.	As a component of repeat use food-contact articles in contact with aqueous, acidic and low-alcohol foods (alcohol content not exceeding 15 %) at temperatures not exceeding 49°C.
1999-022	Keller and Heckman on behalf of Mitsui Chemicals Inc.	A copolymer consisting of linear low density polyethylene complying with 21 CFR 177.1520(c), item 3.2, which has been subsequently grafted with 0.8% or less by weight of maleic anhydride.	The intended use would involve the blending of the subject additive at levels up to 15 weight percent with other polyolefins complying with 21 CFR 177.1520 to form a polymeric film with a maximum thickness of 1 mil. The blended polymeric film would function either as the adhesive non food-contact inner-layer or as the heat seal food-contact layer in multilayered packaging that will be approximately 4 mils thick and used to hold processed meat during and after cooking.
1999-021	Environ on behalf of ICI Polyurethanes	Three polymeric diphenyl-methane diisocyanate (PMDI) formulations consisting mainly of PMDI (CAS Reg. No. 9016-87-9) and 4,4'-methylenediphenyl diisocyanate (MDI) (CAS Reg. No. 101-68-8). The three PMDI formulations would contain up to 53% PMDI and 52% MDI.	For use as strengthening agents at levels up to 1% by weight in paper and paperboard (coated and uncoated) in contact with aqueous food at temperatures that do not exceed 120°F.
1999-020	Keller and Heckman on behalf of Ferro Corporation	Solvent Yellow 72 (CAS Reg. No. 4645-07-2) and Disperse Orange 47 (CAS Reg. No. 5718-26-3)	Solvent Yellow 72 and Disperse Orange 47 as colorants at levels up to 0.39% and 0.30% by weight, respectively, in foamed polystyrene articles used in contact with all types of food, including meat, fish and poultry, under the following conditions: (1) Conditions of Use F and G; (Table 2, 21 CFR 176.170) and (2) Condition of Use E for storage times of one hour or less.
1999-019	Keller and Heckman	C.I. Solvent Blue 36 (CAS Reg. No. 14233-37-5)	As a colorant at levels up to 0.011 % by weight in foamed polystyrene articles used in contact with all types of food under refrigerated temperatures and below (Conditions of Use F and G; Table 2, 21 CFR 176.170).
1999-018	Keller and Heckman on behalf of ReedSpectrum	Solvent Red 26 (CAS Reg. No. 4477-79-6)	As a colorant at levels up to 0.2 % by weight in foamed polystyrene articles used in contact with all types of food, including meat and poultry, under refrigerated temperatures and below (Conditions of Use F and G; Table 2, 21 CFR 176.170).
1999-017	Technogenia Inc.	An alloy consisting of tungsten carbide (68% by weight) and a matrix of nickel (11.2% or less by weight), chromium (11% or less by wt.), iron (3.6% or less by wt.) boron(2% or less by wt.), silicon (3.5% or less by wt.) and trace amounts of carbon (0.6% or less by wt.) and cobalt (0.1% or less)	For use in the manufacture of food - processing equipment.
1999-016	Schiff and Company	Copper and copper cobalt	Copper and copper cobalt, at levels up to 0.1% by weight, as dopants in zinc sulfide pigments used at levels up to 10% by weight in plastic cups, plates and disposable cutlery destined for food-contact applications.
1999-015	Elementis Performance Polymers	2-Ethyl-1,3-hexanediol (CAS Reg. No. 94-96-2)	As the diol component of polyurethane adhesives used in the construction of reverse osmosis membranes for filtering water and aqueous-based liquid

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1999-014	Tecknor Color Company	Solvent Red 24 (CAS Reg. No. 85-83-6), Solvent Yellow 72 (CAS Reg. No. 4645-07-2) and Solvent Orange 60 (CAS Reg. No. 6925-69-5)	food provided the reverse osmosis membrane meets all applicable limitations in 21 CFR 177.2550 and the maximum temperature of use does not exceed 140°F.
1999-013	CanTox Incorporated on behalf of Rohm Enzyme Finland	Xylanases (hemicellulase enzyme preparations) manufactured by fermentation of genetically modified strains of Trichoderma Reesei	Solvent Red 24, Solvent Yellow 72 and Solvent Orange 60 as colorants at levels up to 0.15%, 0.045% and 0.025% by weight, respectively, in foamed polystyrene articles used in contact with all types of food, including meat and poultry, under refrigerated temperatures and below (Conditions of Use F and G; Table 2, 21 CFR 176.170).
1999-012	Interplastic Corporation; Silmar Resins Division	Potassium 2-ethylhexanoate (CAS Reg. No. 3164-85-0) and dodecytrimethyl ammonium chloride (CAS Reg. No. 112-00-5)	As pre-bleaching agents for wood pulp used in the manufacture of food-contact paper provided the use level does not exceed 100 Birchwood Xylanase Units (BXU)/g pulp or 100 Thermo Xylanase Units (TXU)/g pulp. (1 BXU or 1 TXU = 1 nanokatal)
1999-011	Lewis and Harrison	(1) A mixture composed of bromochloro-5, 5-dimethyl-hydantoin (CAS Reg. No. 32718-18-6), dichloro-5,5-dimethylhydantoin (CAS Reg. No. 118-52-5) and dichloro-5-ethyl-5-methylhydantoin (CAS Reg. No. 89415-87-2). (2) A mixture composed of dichloro-5,5-dimethyl-hydantoin and dichloro-5-ethyl-5-methylhydantoin	Potassium 2-ethylhexanoate and dodecytrimethyl ammonium chloride, at maximum use levels of 0.075% and 0.03% by weight, respectively, in the manufacture of thermosetting styrenated polyester resins complying with 21 CFR 177.2420 and intended for use as articles or components of articles for repeated use in contact with food , provided the finished resins meet the extractive limitations in 21 CFR 177.2420(c) and the finished articles are thoroughly cleansed prior to their first use in contact with food in accordance with 21 CFR 177.2420(d).
1999-010	National Starch and Chemical Company	Manganese(2+), bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-N1,N4,N7), tri- μ -oxodi-, bis[hexafluorophosphate(1-)] (CAS Reg. No. 116633-52-4)	As slimicides in the manufacture of food-contact paper and paperboard at a maximum use level of 150 ppm expressed on a dry pulp weight basis.
1999-009	Schunk Graphite Technology	Molybdenum disulfide and phenol-formaldehyde resins complying with 21 CFR 177.2410	As a catalyst in the treatment of starch intended for use in the manufacture of paper and paperboard for food-contact applications at a maximum use level of 0.05 μ g/in ² in the finished paper.
1999-008	Frederick Brewing Co.	Diabase rocks (Blue Stone)	For use in the manufacture of carbon-graphite seals for food-processing equipment. The phenol-formaldehyde resins complying with 21 CFR 177.2410, which are used to impregnate the carbon graphite material, must be post-cured if the seals are intended to contact acid foods (pH < 5.0). (The use of phenol-formaldehyde resins, as components of carbon-graphite seals for food processing equipment, in contact with nonacid foods (pH > 5.0) would be covered by 21 CFR 177.2410.)
			For use in the manufacture of beer.

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1999-007	Zeneca Biocides	2-Methyl-4,5-trimethylene-4-isothiazolin-3-one	As a preservative at levels not exceeding 0.015% by weight in water-based adhesives complying with 21 CFR 175.105 for use at temperatures not exceeding 120°F.
1999-006	Keller and Heckman on behalf of Great Lakes Chemical Corporation	BromoChloro-5,5-dimethylhydantoin (equimolar mixture of 1-bromo-3-chloro-5,5-dimethylhydantoin, CAS Reg. No. 16079-88-2; 3-bromo-1-chloro-5,5-dimethylhydantoin, CAS Reg. No. 126-06-7; 1,3-dibromo-5,5-dimethylhydantoin, CAS Reg. No. 77-48-5; and 1,3-dichloro-5,5-dimethylhydantoin, CAS Reg. No. 118-52-5)	As a slimicide in the manufacture of food-contact paper and paperboard at a maximum use level of 150 ppm on a dry pulp weight basis. As a slimicide in the manufacture of food-contact paper and paperboard at a maximum use level of 150 ppm by weight expressed on a dry solids basis (i.e., pulp, fillers and other materials found in the finished paper) provided the dimethylhydantoin hydrolysis product of the additive is not substantive to the pulp, fillers or any other additive remaining with the finished paper.
1999-005	S.I. Graham and Associates	3-Iodo-2-propynyl butyl carbamate	As a biological growth control agent at a maximum use level of 1% by weight in pressure sensitive adhesive formulations complying with 21 CFR 175.125.
1999-004	Lewis and Harrison Consultants	Tetrakis(hydroxymethyl)phosphonium sulfate (CAS Reg. No. 55566-30-8)	At a maximum concentration of 500 ppm as a preservative for alkyl ketene dimer (AKD) emulsions applied to food-contact paper at the dry end of the paper machine.
1999-003	Keller and Heckman on behalf of FMC Corporation	1-Hydroxyethylidene-1,1-diphosphonic acid	At levels not exceeding 14 ppm (expressed on a dry pulp basis) as a stabilizer in antimicrobial agent formulations used in the manufacture of food-contact paper.
1999-002	Keller and Heckman on behalf of Solvay Interrox Inc.	1-Hydroxyethylidene-1,1-diphosphonic acid (HEPA) and dipicolinic acid	HEPA and dipicolinic acid at levels not exceeding 7000 ppm and 300 ppm, respectively, (7.0 ppm and 0.3 ppm when expressed on a dry pulp basis) as stabilizers in antimicrobial agent formulations used in the manufacture of food-contact paper.
1999-001	Lewis and Harrison Consultants on behalf of Albright and Wilson Americas, Inc.	Methylene bis(thiocyanate) and xanthan gum	As components of an adhesive preservative. The adhesive will be used in packaging materials for dry foods only and the use level of the methylene bis thiocyanate and xanthan gum will not exceed 0.01% and 0.0004% by weight of the adhesive.
1998-026	Industrial Wear Reduction Systems	Triisodecyl tridecyl trimellitic ester (CAS Reg. No. 70225-05-7) and trimethylol propane-trioleate ester of isostearic acid	As components of lubricants applied to the wheels of overhead trolley-type conveyors found in meat and poultry plants, provided the level of use and frequency of application is limited to good manufacturing practice (i.e., the minimum level needed to accomplish the intended technical effect).
1998-025	John Crane, Inc.	Neodymium fluoride, toluidinequinone, 1-methoxy-2-propanol, and dicyclopentadiene	As components of impregnated carbon-graphite composites intended for use in the manufacture of mechanical and shaft seals used in food processing equipment.

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1998-024	Technology Sciences Group, Inc. on behalf of Wacker Silicones/Wacker Chemie GmbH.	Hexamethyl disilazane-treated silica (CAS Reg. No. 68909-20-6) and hexamethyl - disilazane/divinyl tetramethyl-disilazane - treated silica (CAS Reg. No. 68988-89-6)	As components of antifoam formulations used in the manufacture of the following food-contact articles (i.e., paper, adhesives, and polymer coatings destined for use on paper and metal substrates) provided the maximum use level does not exceed 0.005% by weight.
1998-023	Keller and Heckman on behalf of ReedSpectrum	Pigment Red 202 (CAS Reg. No. 3089-17-6)	As a colorant at levels up to 0.15 % by weight in polyethylene terephthalate articles, including dual-ovenable trays, used in contact with all types of food at baking temperatures and below.
1998-022	Keller and Heckman on behalf of ReedSpectrum	Pigment Red 247 (CAS Reg. No. 43035-18-3)	As a colorant at levels up to 1.3 % by weight in polyethylene terephthalate articles, including dual-ovenable trays, used in contact with all types of food at baking temperatures and below.
1998-021	Center For Regulatory Services	Polyglycerol esters of fatty acids regulated in 21 CFR 172.854.	As antifogging agents in polyolefin films complying with 21 CFR 177.1520 at a maximum use level of 0.152 mg/in ² .
1998-020	Keller and Heckman on behalf of Hydranautics.	Polyvinyl alcohol (PVA) cross-linked with 1,3,5-benzenetricarbonyl trichloride and piperazine	At a maximum use level of 16% by weight as a component of the barrier layer of reverse osmosis membranes complying with 21 CFR 177.2550.
1998-019	Paper Chemicals Inc.	Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyl)dinitrilo)tetrakis(propanol) (CAS Reg. No. 11111-34-5)	For use as a defoamer or as a component of a defoamer during the manufacture of food-contact paper products, provided its use level at the washing stage of the pulp does not exceed 0.5 lb/ton of pulp.
1998-018	S.I. Graham and Associates on behalf of FTI Inc.	N,N'-ethylene-bis-12-hydroxystearamide (CAS Reg. No. 123-26-2)	At a maximum use level of 0.35% by weight in lubricants intended for incidental food contact (21 CFR 178.3570).
1998-017	Keller and Heckman on behalf of Engelhard Corporation	The strontium salts of the azo coupling reaction products formed between either: (1) 6-hydroxynaphthalene-2-sulfonic acid (CAS Reg. No. 93-01-6) and a mixture of 2-amino-4-ethyl-5-chlorobenzenesulfonic acid (CAS Reg. No. 88-56-2) and 2-chloro-4-aminotoluene-5-sulfonic acid (CAS Reg. No. 88-51-7); or (2) 6-hydroxynaphthalene-2-sulfonic acid and p-aminobenzoic acid (CAS Reg. No. 150-13-0)	For use as colorants at levels up to 1% by weight in all polymers contacting non-fatty food under Conditions of Use A through H (Table 2, 21 CFR 176.170) and in all polymers contacting fatty food under Condition of Use C or below.
1998-016	TAS-Environ on behalf of ICI Polyurethanes	A mixture of polymeric diphenylmethane diisocyanate (PMDI; CAS Reg. No. 9016-87-9) and modified PMDI (PMDI modified with either methoxypolyethylene glycol (PMDI/MPG; CAS Reg. No. 70644-56-3) or ethoxylated, propoxylated ethylenediamine (PMDI/EDA/EO/PO, CAS Reg. No. 68403-89-4))	As a dry-strength agent in paper and paperboard intended to contact dry foods only, provided the concentration does not exceed 5 percent by weight of the dry paper and paperboard and the temperature does not exceed 120°F).
1998-015	Keller and Heckman on behalf of NOVA Chemical Inc.	1-hydroxy-4-((4-methylphenyl)amino)-9,10-anthracenedione (CAS Reg. No. 81-48-1).	At levels not to exceed 0.2 ppm in polystyrene food-contact articles.
1998-014	Keller and Heckman on behalf of ReedSpectrum	C.I. Solvent Orange 60 (CAS Reg. No. 6925-69-5)	As a colorant at levels up to 0.015 % by weight in foam polystyrene articles used in contact with all types of food, including meat and poultry, under refrigerated temperatures and below (Conditions of Use F and G; Table 2, 21 CFR 176.170).

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1998-013	Carpenter Advanced Ceramics, Inc.	Hafnium and strontium oxides	Hafnium and strontium oxides, at levels up to 3% and 0.5% by weight, respectively, in zirconium-based ceramics used as components of food-processing equipment
1998-012	AntiSeize Technology	Zeeospheres (CAS Reg. No. 66402-68-4)	At maximum levels up to 40% by weight in anti-seize lubricants intended for incidental food contact.
1998-011	National Starch and Chemical Co.	Industrial starch-modified (i.e., starch manufactured with up to 5% 2,3-epoxypropyltrimethylammonium chloride in accordance with 21 CFR 178.3520 and further modified with up to 4.5% glycidoxypolytrimethoxysilane.	For use in the manufacture of : (1) Paper towels and napkins destined for single service food-contact applications at temperatures not to exceed 212°F; and (2) Paper/paperboard containers destined to hold food at room temperature (120°F) or below, provided the level of the modified starch in the paper products does not exceed 1% by weight and the finished paper products meet applicable extractive limitations in 21 CFR 176.170.
1998-010	Keller and Heckman on behalf of Englehard Corp.	C.I. Pigment Green 50 (CAS Reg. No. 68186-85-6), C.I. Pigment Yellow 53 (CAS Reg. No. 8007-18-9), and C.I. Pigment Brown 24 (CAS Reg. No. 68186-90-3)	As colorants at levels up to 2% by weight in all types of food-contact polymers. The finished polymers may be used in contact with all food types under Conditions of Use A through H (as described in Table 2, 21 CFR 176.170(c)).
1998-009	Center For Regulatory Services on behalf of Unitika Composite Films Ltd.	Polyoxypropylene ethers of 4,4'-isopropylidenediphenol (CAS Reg. No. 37353-75-6)	As a component of adhesive formulations, at a maximum use level of 0.03% by weight in composite films complying with §177.1390 and §177.1395, provided the adhesive is separated from food by a polyolefin layer with a thickness not less than 1.6 mils.
1998-008	Keller and Heckman on behalf of ReedSpectrum	C.I. Solvent Red 23 (CAS Reg. No. 85-86-9)	As a colorant at levels up to 0.055 % by weight in foam polystyrene articles used in contact with all types of food, including meat and poultry, under refrigerated temperatures and below (Conditions of Use F and G; Table 2, 21 CFR 176.170).
1998-007	Keller and Heckman on behalf of ReedSpectrum	C.I. Pigment Red 254 (CAS Reg. No. 84632-65-5)	As a colorant at levels up to 0.70 % by weight in polyethylene terephthalate articles, including dual-ovenable trays, used in contact with all types of food under Conditions of Use A through H (Table 2, 21 CFR 176.170).
1998-006	Keller and Heckman on behalf of ReedSpectrum	C.I. Pigment Red 187 (CAS Reg. No. 59487-23-9)	As a colorant at levels up to 0.18 % by weight in polyethylene terephthalate articles, including dual-ovenable trays, used in contact with all types of food under Conditions of Use A through H (Table 2, 21 CFR 176.170).
1998-005	Keller and Heckman	Polyglycerol esters of fatty acids regulated in 21 CFR 172.854	As antifogging agents in all types of films at a maximum use level of 0.14 mg/in ² .
1998-004	Englehard Corp.	Tin Oxide	At a maximum level of 1.1% by weight in colorants composed of mica and titanium dioxide, provided the maximum loading rate for the colorant in the food-contact article does not exceed 3% by weight for polymers, 5% for paper and

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1998-003	BetzDearborn Inc.	Sodium molybdate	paperboard, 15% for coatings or 30% for ink formulations.
1998-002	Nutra Sweet Kelco Company	Gellan gum	As a tracer, at an equilibrium concentration of 5 ppm for molybdate ion, in boiler water used to produce steam destined to cook food.
1998-001	Keller and Heckman on behalf of Tioxide Group PLC.	N-Octylphosphonic acid-modified titanium dioxide	For use as a sizing agent or as a component of coatings for paper and paperboard destined to contact all types of food provided: (1) The gellan gum meets the specifications in paragraphs (a) through (d) in 21 CFR 172.665; (2) its use levels are restricted to GMP levels; and (3) the finished paper products meet applicable extractive limitations in 21 CFR 176.170.
1997-018	McDermott, Will and Emery	Phenol red (CAS Reg. No. 143-74-8), cresol red (CAS Reg. No. 1733-12-6) and m-cresol purple (CAS Reg. No. 2303-01-7)	As a colorant at levels not exceeding 5% by weight in polymers contacting all types of food under Condition of Use C, Table 2, 21 CFR 176.170 (hot filled or pasteurized above 150° F) or less severe conditions.
1997-017	Lifelast, Inc.	Methylene-bis-cyclohexamine (CAS Reg. No. 1761-71-3) and sucrose amine polyether polyol (CAS Reg. No. 25214-63-5)	Phenol red, cresol red, and m-cresol purple, either alone or as a mixture at a maximum level of 2 µg, as components of "freshness sensor" labels that would contact meat, fish, and poultry as well as juice and dairy beverages at refrigerated temperatures. Before use, the backing would be removed and the label applied to food packaging composed of either polyvinyl chloride (PVC) or linear low density polyethylene (LDPE). Therefore, under the intended use conditions, the dye would always be separated from food by PVC or LDPE.
1997-016	Keller and Heckman on behalf of Hydranautics	Polyvinyl alcohol crosslinked with 1,3,5-benzenetricarbonyl trichloride and 1,3-benzenediamine	Methylene-bis-cyclohexamine and sucrose amine polyether polyol as components of polyurethane coatings at maximum use levels of 1.15% and 3.75% by weight, respectively. The polyurethane coatings would be limited to repeat-use applications involving dry food at room temperature (120°F or below).
1997-015	NA Industries, Inc.	Copolymer of methyl methacrylate (90% by weight) and trimethylolpropane trimethacrylate (10% by weight)	At a maximum use level of 16% by weight as a component of the barrier layer of reverse osmosis membranes complying with 21 CFR 177.2550.
1997-014	Withdrawn	_____	As an antiblocking agent at a maximum use level of 1% by weight in thin polypropylene films (i.e., a maximum thickness of 4 mils) destined for use in contact with all types of food under Conditions of Use A through H (Table 2, 21 CFR 176.170).
1997-013	Washington Trading Company, Inc.	Benzyl alcohol, isobutyl alcohol, amyl alcohol and benzyl acetate	_____
			Benzyl alcohol, isobutyl alcohol, amyl alcohol and benzyl acetate at maximum use levels of 1.9%, 1.7 %, 4.5% and 0.1% by weight, respectively, as components of lubricants for incidental food contact complying with 21 CFR 178.3570.

File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
1997-012	Inter - American Nexus, Inc.	Dimethylpolysiloxane (CAS Reg. No. 9016-00-6), polyethylene glycol monostearate (CAS Reg. No. 9004-99-3) and xanthan gum (CAS Reg. No. 11138-66-2)	Dimethylpolysiloxane, polyethylene glycol monostearate and xanthan gum at maximum use levels of 24%, 3% and 0.08% by weight, respectively, as components of release coatings for metal substrates that are reapplied as frequently as every eight hours and are used in oven baking of large quantities of food.
1997-011	Keller and Heckman on behalf of DuPont Dow Elastomers	4,4'-(Hexafluoroisopropylidene)diphenol (bisphenol AF) (CAS Reg. No. 1478-61-1) and benzyltriphenylphosphonium bisphenol AF salt (CAS Reg. No. 75768-65-9)	Bisphenol AF at a use level of 2% by weight and benzyltriphenyl phosphonium bisphenol AF salt at a use level of 1.9% by weight as vulcanization agents in the manufacture of vinyl fluoride-hexa - fluoropropylene and vinyl fluoride-hexa - fluoropropylene - tetrafluoroethylene copolymers regulated in 21 CFR 177.2600 destined for use in the manufacture of repeat-use rubber articles that may contact all types of food at temperatures up to 250°F
1997-010	Courtaulds Coatings. Ltd	Aromatic petroleum resins (CAS Reg. No. 71302-83-5) manufactured from indene, α-methylstyrene and vinyl toluene.	As a component of coatings complying with 21 CFR 175.300 for contact with dry food provided the level of the resin in the cured coatings does not exceed 1.5% by weight.
1997-009	ACC Consulting Group, Inc., on behalf of Adhesives Research Inc.	Acrylic copolymers (consisting of isoctyl acrylate (CAS Reg. No. 29590-42-9), ethoxylated hydroxyethyl methacrylate (CAS Reg. No. 25736-86-1) and monomers regulated in 21 CFR 177.1010 (a)(1), (2) and (3)) and D&C Green No. 5 (CAS Reg. No. 4403-90-1)	As adhesive components in pressure-sensitive tape for use in splicing paper that will subsequently be repulpable and used in the manufacture of food-contact paper complying with 21 CFR 176.170. The isoctyl acrylate and ethoxylatedhydroxyethyl methacrylate monomers must not make up more than 25% and 30% by weight, respectively, of the acrylic copolymer units and at least 50% by weight of the finished acrylic acid copolymer units must be derived from one or more of the following monomers (isoctyl acrylate, ethoxylated hydroxyethyl methacrylate, and the monomers listed in 21 CFR 177.1010 (a)(1)). The use level of the D&C Green No. 5 must not exceed 500 ppm in the dry adhesive.
1997-008	Carter, Ledyard and Milburn on behalf of Sweetheart Cup Co.	Acetone	As a blowing agent at levels up to 1.1% by weight in the manufacture of polystyrene food-contact articles.
1997-007	Betz Laboratories	Sodium molybdate	For use at an equilibrium concentration of 2 ppm in boiler water used to produce steam destined to cook food.
1997-006	Champion International Corporation	Pulp containing benzenesulfonic acid, 2,2'-(1,2-ethanediyl)bis(5-(4-(bis(2-hydroxyethyl)amino)-6-((4-sulfophenyl)amino)-1,3,5-triazine-2-yl)amino)-, tetrasodium salt, CAS Reg. No. 16470-24-9	Pulp containing up to 20 ppb of benzenesulfonic acid, 2,2'-(1,2-ethanediyl)bis(5-(4-(bis(2-hydroxyethyl)amino)-6-((4-sulfophenyl)amino)-1,3,5- triazine-2-yl)amino)-, tetrasodium salt, used in the manufacture of food-contact paper products.
1997-005	National Starch and Chemical Co.	3-Chloro-2-sulfopropionic acid-treated starch	For use at levels up to 1.5% by weight in paper towels and napkins destined for single service food-contact applications at temperatures not to exceed 212°F.

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1997-004	Dow Chemical	An ion exchange resin manufactured by the reaction of divinyl benzene, methyl acrylate and butyl acrylate followed by complete hydrolysis of the methyl and butyl ester side chains (CAS Reg. No. 9052-45-3)	For repeated-use food-contact applications involving potable water and aqueous, acidic and alcoholic foods at temperatures of 82°C (180°F) or below. The resin must be prewashed in accordance with good manufacturing practice and meet all applicable specifications in 21 CFR 173.25(c).
1997-003	Texapol Corp.	Melamine (CAS Reg. No. 108-78-1) and triphenyl phosphine (CAS Reg. No. 603-35-0)	Melamine at a use level of 0.2% by weight and triphenylphosphine at a use level of 0.05% by weight as stabilizers in polyoxymethylene copolymers regulated in 21 CFR 177.2470 destined for use in the manufacture of repeat-use articles that may contact food.
1997-002	Keller and Heckman on behalf of Reedspectrum	2,4-dihydro-4-((2-methoxyphenyl)azo)-5-methyl-2-phenyl-3H-pyrazol-3-one (CAS Reg. No. 4645-07-2)	As a colorant at levels up to 0.0228% by weight in foamed polystyrene used to package all types of food, including meat and poultry, at refrigerated temperatures or below (Conditions of Use F and G, Table 2, 21 CFR 176.170).
1997-001	Chemtest Laboratories Inc., on behalf of Sunkyong Industries	Trimellitic anhydride	As a crosslinking agent at a use level of 0.04% by weight in the manufacture of polyethylene terephthalate/isophthalate copolymers containing 67.7 weight percent terephthalic acid, 2.7 weight percent isophthalic acid and 29.7 weight percent ethylene glycol destined for use in contact with all types of food at room temperature (120°F) or below.
1996-009	TAS Inc., on behalf of Johnson Matthey Chemicals	Silver chloride-coated titanium dioxide	As a component of preservative formulations for latex emulsions destined for use in the manufacture of repeat-use rubber articles regulated in 21 CFR 177.2600 provided the levels of silver chloride added to the latex emulsions do not exceed 10 ppm.
1996-008	Dover Chemical Corp.	Bis(2,4-dicumylphenyl) pentaerythritol diphosphite (CAS Reg. No. 154862-43-8)	As an antioxidant/stabilizer at levels not exceeding 0.1% by weight in polypropylene polymers and copolymers complying with 21 CFR 177.1520 destined to contact aqueous, acidic and low alcohol foods (15% or less) under Condition of Use C (hot filled or pasteurized above 150°F)(Table 2, 21 CFR 176.170). This exemption would cover both single-service and repeat-use applications.
1996-007	Center for Regulatory Services on behalf of Riken Vitamin Company Ltd., of Japan.	Polyglycerol esters of fatty acids regulated in 21 CFR 172.854	As an adjuvant (e.g., antifogging agent, antistatic agent) in polypropylene films regulated in 21 CFR 177.1520 and having a maximum thickness of 100 um in contact with all types of food under Conditions of Use A through H (Table 2, 21 CFR 176.170).
1996-006	Ciba - Geigy Corp.	Bis(2,4-di-tert-butyl-6-methylphenyl)ethyl phosphite (CAS Reg. No. 145650-60-8)	For use as a processing stabilizer at levels up to 0.2% by weight in polypropylene destined to contact aqueous, acidic and low alcohol food (8% or less) at temperatures at or below 212° F.
1996-005	S.C. Johnson and Son, Inc.	Acrylic polymers consisting of methacrylic acid, methyl methacrylate, and 2-ethylhexyl acrylate in which the methacrylic acid is present at	As a moisture barrier coating of paper in contact with aqueous or fatty food at temperatures at or below 120° F

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		levels not exceeding 9% by weight and the 2-ethylhexyl acrylate and methyl methacrylate are present at no less than 50% by weight of the finished polymer in accordance with 21 CFR 177.1010	provided the finished paper meets the applicable extractives limitations of 21 CFR 176.170.
1996-004	Zeneca Biocides	Poly(hexamethylenebiguanide) hydrochloride (CAS Reg. No. 32289-58-0)	As an antimicrobial agent at levels up to 1000 ppm (0.1% by weight) in water-based latex adhesives complying with 21 CFR 175.105 for use at temperatures that do not exceed 120°F.
1996-003	Selective Services, Ltd.	Di(2-ethylhexyl)sebacate (CAS Reg. No. 122-62-3)	As a component of oil-based lubricants at levels up to 5% by weight. The exemption would be limited to use in lubricants with only incidental contact with food in accordance with 21 CFR 178.3570.
1996-002	Morgan, Lewis and Bockius on behalf of Chesapeake Paper Products, Inc.	C.I. solvent blue 129 (CAS Reg. No. 68155-92-0), C.I. solvent yellow 143 (CAS Reg. No. 68239-62-3), 1-propanol, and silanol (CAS Reg. No. 70131-67-8)	As components of ink formulations used to mark pulp bale wrappers that will subsequently be repulped and used in the manufacture of food-contact paper provided the maximum use levels in the ink formulations do not exceed 3% by weight in the case of the C.I. solvent blue 129 and 1-propanol components and 1% by weight for the C.I. solvent yellow 143 and silanol components.
1996-001	Hogan and Hartson on behalf of Gycor International Limited.	Tetrasodium ethylenediaminetetraacetate (tetrasodium EDTA) (CAS Reg. No. 64-02-8)	As a chelator in place of disodium EDTA in a sanitizing solution codified in § 178.1010(b)(44) and (c)(38) (Final rule: 60 FR 18739) provided its "at use" concentration in the sanitizer does not exceed 1400 ppm and the use of the sanitizer is restricted to clean-in-place food-processing equipment and utensils including its use on dairy-processing equipment. Exemption does not include the use in public eating establishments.

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*For references to food types and conditions of use, see [Food Types & Conditions of Use for Food Contact Substances¹²](#)

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Page Last Updated: 04/17/2024

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