FDA

Threshold of Regulation (TOR) Exemptions

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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 (premarkt@fda.hhs.gov).

More about food contact substances[5].

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File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
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 on food packaging 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.

File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
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, optionally with a sublayer comprised of hydrogenated amorphous silicon-carbide alloy	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 to reduce surface wear, friction, and sticking of food to materials. The FCS is not for use in contact with infant formula. 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.

File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
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 substance in the TOR exemption request.
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.

File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
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 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.
2017-003	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)	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.
2017-002	GRAS Associates, LLC on behalf of REMA TIP TOP/North America, Inc.	Isocyanic acid, polymethylenepolyphenylene ester (PMDI) (CAS Registry Number 9016-87-9)	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.
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 the substance 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.

File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
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.
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.

File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
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-cyclohexanedimethanol, 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-cyclohexanedimethanol 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 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).

File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
2014-001	Interplastic Corporation	4-hydroxy-2,2,6,6-tetramethylpiperidinooxy (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)propyldimethyloctadecyl 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: 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), 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)	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.

File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
2011-002	Keller and Heckman, LLP.	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)	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	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: 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 or coatings intended for use in contact with all foods under use conditions up to and including cooking.

File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
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. 119345-04-0)	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.

File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
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 *Hydrogen peroxide*.
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. 6861-51-5)	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).

File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
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. 4. Polybutylene, complying with §177.1570, as a component of the food contact layer of the laminate. 5. An urethane adhesive, provided it complies with §175.105, as a component of the adhesive, non-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)
2005-007	Mitec Advanced Technology	Polystyrene foam tray with a multi-layer food-contact coating. The coating may contain: 1. The following substances as long as they meet the applicable use level limitations in §178.2010 or an effective notification: 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-butyphenyl)phosphite (CAS Reg. No. 31570-04-4) 6. Cyclic neopentanetetrayl 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). 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).

File (sorted Z-A)	Requestor	Food Contact Substance	Use Limitations*
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.

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*For references to food types and conditions of use, see Food Types & Conditions of Use for Food Contact Substances[12]

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