DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

THRESHOLD OF REGULATION EXEMPTIONS

ISSUED UNDER 21 CFR 170.39

FILE	COMPANY	CHEMICALS	USE LIMITATIONS
96-001	Hogan and Hartson on behalf of Gycor International Limited.	Tetrasodium ethylenediamine tetraacetate (tetrasodium EDTA) (Chemical Abstract Service Registry Number 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.
96-002	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.
96-003	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.
96-004	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.
96-005	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 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	As a moisture barrier coating of paper in contact with aqueous or fatty food at temperatures at or below 120° F provided the finished paper meets the applicable extractives limitations of 21 CFR 176.170.
96-006	Ciba-Geigy Corp	Bis(2,4-di-tert-butyl-6-methyl phenyl) ethyl phosphite (CAS Reg. No. 145650-60-Q	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.
96-007	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).
96-008	Dover Chemical Corporation	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.

FILE	COMPANY	CHEMICALS	USE LIMITATIONS
96-009	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.
97-001	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.
97-002	Keller and Heckman on behalf of Reedspectrum	2,4-dihydro-4-[(2-methoxy phenyl)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).
97-003	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.
97-004	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. 009052-45-3	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).
97-005	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.
97-006	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.
97-007	Betz Laboratories	Sodium molybdate	For use at an equilibrium concentration of 2 ppm in boiler water used to produce steam destined to cook food.
97-008	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.

FILE	COMPANY	CHEMICALS	USE LIMITATIONS
97-009	ACC Consulting Group, Inc., on behalf of Adhesives Research Inc.	Acrylic copolymers (consisting of isooctyl acrylate (CAS Reg. No. 29590-42-9), ethoxylated hydroxyethyl methacrylate (CAS Reg. No. 25736-86-l) and monomers regulated in 2 1 CFR 177.1010 (a)(l), (2) and (3)) and D&C Green No. 5 (CAS Reg. No. 4403-90-I)	As adhesive components in pressure-sensitive tape for use in splicing paper that will subsequently be repulped and used in the manufacture of food-contact paper complying with 21 CFR 176.170. The isooctyl acrylate and ethoxylated hydroxyethyl 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 (isooctyl acrylate, ethoxylated hydroxyethyl methactylate, and the monomers listed in 21 CFR 177.1010 (a)(l)). The use level of the D&C Green No. 5 must not exceed 500 ppm in the dry adhesive.
97-010	Courtaulds Coatings. Ltd	Aromatic petroleum resins (CAS Reg. No. 71302-83-5) manufactured from indene, alpha-methylstyrene and vinyl toluene.	As a component of coatings complying with 2 1 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.
97-011	Keller and Heckman on behalf of DuPont Dow Elastomers	4,4'-(hexafluoroisopropylidene)-diphenol (bisphenol AF) (CAS Reg. No. 1478-61-i) and benzyltriphenylphosphonium bisphenol AF salt (CAS Reg. No. 75768-65-9)	Bisphenol AF at a use level of 2% by weight and benzyltriphenylphosphonium bisphenol AF salt at a use level of 1.9% by weight as vulcanization agents in the manufacture of vinyl fluoride-hexafluoropropylene and vinyl fluoride-hexafluoropropylene-tetrafluoroethylene copolymers regulated in 2 1 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.
97-012	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.
97-013	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.
97-014	Withdrawn	----------	----------
97-015	NA Industries. Inc.	Copolymer of methyl methacrylate (90% by weight) and trimethylolpropane trimethacrylate (10% by weight)	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).
97-016	Keller and Heckman on behalf of Hydranautics	Polyvinyl alcohol crosslinked with 1,3,5-benzenetricarbonyl trichloride and 1,3-benzenediamine	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.

FILE	COMPANY	CHEMICALS	USE LIMITATIONS
97-017	Lifelast, Inc.	Methylene-bis-cyclohexamine (CAS Reg. No. 1761-71-3) and sucrose amine polyether polyol (CAS Reg. No. 25214-63-5)	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).
97-018	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)	Phenol red, cresol red. and m-cresol purple, either alone or as a mixture at a maximum level of 2 ug, 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.
98-00 1	Keller and Heckman on behalf of Tioxide Group PLC.	N-octylphosphonic acid-modified titanium dioxide.	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 tilled or pasteurized above 150° F) or less severe conditions.
98-002	Nutra Sweet Kelco Company	Gellan gum	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 2 I 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.
98-003	BetzDearborn, Inc.	Sodium molybdate	As a tracer, at an equilibrium concentration of 5 ppm for molybdate ion. in boiler water used to produce steam destined to cook food.
98-004	Engelhard 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 paperboard. 15% for coatings or 30% for ink formulations.
98-005	Keller and Heckman	Polyglycerol esters of fatty acids regulated in 2 1 CFR 172.854	As antifogging agents in all types of films at a maximum use level of 0.14 mg/in^2.
98-006	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 terephthlate articles. including dual-ovenable trays, used in contact with all types of food under Conditions of Use A through H (Table 2, 2 1 CFR 176.170).
98-007	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 terephthlate 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).

FILE	COMPANY	CHEMICALS	USE LIMITATIONS
98-008	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, 2 1 CFR 176.170).
98-009	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.
98-010	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.
98-O 11	National Starch and Chemical Co.	Industrial starch-modified (i.e., starch manufactured with up to 5% 2,3-epoxypropyltrimethyl-ammonium chloride in accordance with 2 1 CFR 178.3520 and further modified with up to 4.5% glycidoxypropyl-trimethoxysilane	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.
98-012	Anti-Seize 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.
98-013	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.
98-014	Keller & Heckman on behalf of ReedSpectrum	C.I. Solvent Orange 60 (CAS Reg. No. 6925-69-5)	As a colorant at levels up to 0.0 15 % 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).
98-015	Keller & Heckman on behalf of NOVA Chemical Inc.	1-hydroxy-4-[(4-methylphenyl)amino]-9,10-anthracenedione (CAS Reg. No. 81-48-l)	At levels not to exceed 0.2 ppm in polystyrene food-contact articles.

FILE	COMPANY	CHEMICALS	USE LIMITATIONS
98-016	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 .
98-017	Keller and Heckman on behalf of Engelhard Corporation	The strontium salts of the azo coupling reaction products formed between either: (1) 6-hydroxy-naphthalene-2-sulfonic acid (CAS Reg. No. 93-01-6) and a mixture of 2-amino-4-ethyl-5-chloro-benzene-sulfonic acid (CAS Reg. No. 88-56-2) and 2-chloro-4-aminotoluene-5-sulfonic acid (CAS Reg. No. 88-5 l-7)); or (2) 6-hydroxy-naphthalene-2-sulfonic acid and p-aminobenzoic acid (CAS Reg. No. 150-13-o)	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.
98-018	S.I. Graham and Associates on behalf of FTI Inc.	N,N'-ethylene bis-12-hydroxystearamide (CAS Reg. No. 123-26-6)	At a maximum use level of 0.35% by weight in lubricants intended for incidental food contact (21 CFR 178.3570).
98-019	Paper Chemicals Inc.	Oxirane, methyl-. polymer with oxirane, ether with (1,2-ethanediyldinitrilo) 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.
98-020	Keller and Heckman on behalf of Hydranautics.	Polyvinyl alcohol (PVA) crossed-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.
98-02 1	Center For Regulatory Services	Polyglycerol esters of fatty acids regulated in 2 1 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.
98-022	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 terephthlate articles, including dual-ovenable trays, used in contact with ail types of food at baking temperatures and below.

FILE	COMPANY	CHEMICALS	USE LIMITATIONS
98-023	Keller and Heckman on behalf of ReedSpectrum	Pigment Red 202 (CAS Reg. No. 3089-l 7-6)	As a colorant at levels up to 0.15 % by weight in polyethylene terephthlate articles, including dual-ovenable trays. used in contact with all types of food at baking temperatures and below.
98-024	Technology Sciences Group, Inc. on behalf of Wacker Silicones/Wacker Chemie GmbH.	Hexamethyldisilazane-treated silica (CAS Reg. No. 68909-20-6) and hexamethyl-disilazane/divinyltetramethyl-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.
98-025	John Crane, Inc.	Neodymium fluoride, toluhydroquinone. 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.
98-026	Industrial Wear Reduction Systems	Triisodecyltridecyltrimellitic ester (CAS Reg. No. 70225-05-7) and trimethylolpropane-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).
99-00 I	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.
99-002	Keller and Heckman on behalf of Solvay lnterox Inc.	I-Hydroxy-ethylidene- I, 1-diphosphonic acid (HEPA) and dipicolinic acid	HEPA and dipicolinic acid at levels not excceding 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.
99-003	Keller and Heckman on behalf of FMC Corporation	1-Hydroxy-ethylidene-1,1-diphosphonic acid	At levels not excceding 14 ppm (expressed on a dry pulp basis) as a stabilizer in antimicrobial agent formulations used in the manufacture of food-contact paper.
99-004	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.
99-005	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.

FILE	COMPANY	CHEMICALS	USE LIMITATIONS
99-006	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-I-chloro-5,5-dimethyl-hydantoin, 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.
99-007	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 that do not exceed 120° F.
99-008	Frederick Brewing co.	Diabase rocks (Blue Stone)	For use in the manufacture of beer.
99-009	Schunk Graphite Technology	Molybdenum disulfide and phenol-formaldehyde resins complying with 21 CFR 177.2410	For use in the manufacture of carbon-graphite seals for food-processing equipment. The phenol-formaldehyde resins complying with 21 CFR 177.24 IO, 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.)
99-o IO	National Starch and Chemical Company	Manganese(2+), bis(octahydro-1,4,7-trimethyl-I H-1,4,7-triazonine (N1, N4, N7), tri-μ-oxodi-. bis[hexafluoro-phosphate(1-)] (CAS Reg. No. 116633-52-4)	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 $\mu g/in^2$ in the finished paper.
99-011	Lewis and Harrison	(I) 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. 894 15-87-2). (2) A mixture composed of dichloro-5,5-dimethyl-hydantoin and dichloro-5-ethyl-5-methylhydantoin	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.

FILE	COMPANY	CHEMICALS	USE LIMITATIONS
99-012	Interplastic Corporation; Silmar Resins Division	Potassium 2-ethylhexanoate (CAS Reg. No. 3 164-85-O) and dodecyltrimethyl ammonium chloride (CAS Reg. No. 112-00-5)	Potassium 2-ethylhexanoate and dodecyltrimethyl 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).
99-013	CanTox Incorporated on behalf of Rohm Enzyme Finland	Xylanases (hemicellulase enzyme preparations) manufactured by fermentation of genetically modified strains of Trichoderma Reesei	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 I TXU = 1 nanokatal)
99-014	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)	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).
99-015	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 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.
99-016	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.
99-017	Technogenia Inc.	An alloy consisting of tungsten carbide (68% by weight) and a matrix of nickel (11.2% or less by weight), chromium (1 1% 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.
99-018	Under review		
99-019	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, 2 1 CFR 176.170).

FILE	COMPANY	CHEMICALS	USE LIMITATIONS
99-020	Keller and Heckman on behalf of Ferro Corporation	Solvent Yellow 72 (CAS Reg. No. 4645-07-2) and Disperse Orange 47 (CAS Reg. No. 57 18-26-3)	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.

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HFA-305
Rm 136
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Attached is an undated list of substances exempted from the food additive listing regulation requirement under FDA's Threshold of Regulation Policy (21 CFR 170.39). Please add this list to Docket Number **92S-0181.** Please note that all of the new projects qualified for a categorical exclusion from the requirement of having to contain an environmental assessment. Therefore, none of these projects have an EA or FONSI for display. Please continue to send me a copy of the updated log for **92S-0181.** Please call me at 202-418-3085 if you have any questions.

Ed Machuga

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