Food and Drug Administration, HHS § 177.1390

(a) The high-temperature laminates identified in this section may be safely used for food contact at temperatures not exceeding 135 °C (275 °F) unless otherwise specified. These articles are layered constructions that are optionally bonded with adhesives. The interior (food-contact) layer(s) may be separated from the exterior layer(s) by a functional barrier, such as aluminum foil. Upon review of the physical properties of a particular construction, the Food and Drug Administration may consider other layers to serve as functional barriers. This regulation is not intended to limit these constructions as to shape, degree of flexibility, thickness, or number of layers. These layers may be laminated, extruded, co-extruded, or fused.

(b) When containers subject to this regulation undergo heat sterilization to produce shelf-stable foods, certain control measures (in addition to the food additive requirements in paragraphs (c) and (d) of this section) are necessary to ensure proper food sterilization and package integrity. Refer to parts 108, 110, 113, and 114 of this chapter for details.

(c) Subject to the provisions of this paragraph, food-contact articles produced from high-temperature laminates may be safely used to package all food types except those containing more than 8 percent ethyl alcohol.

(1) Polymeric films/layers. Films or layers not separated from food by a functional barrier must meet the following requirements:

(i) Films/layers may consist of the following:

(a) Polyolefin resins complying with item 2.2 or 3.2 of the table in §177.1520(c).

(b) Polymeric resin blends formulated from a base polymer complying with item 2.2 or 3.2 of the table in §177.1520(c) blended with no more than 10 percent by weight of a copolymer of ethylene and vinyl acetate complying with §177.1350.

(c) Polymeric resin blends formulated from a base polymer complying with item 2.2 or 3.2 of the table in §177.1520(c) blended with no more than 38 percent by weight of a homopolymer of isobutylene complying with §177.1420(a)(1).

(d) Polyethylene phthalate resins complying with §177.1630(e)(4) (i) and (ii).

(e) Nylon MXD-6 resins that comply with item 10.3 of the table in §177.1500(b) of this chapter when extracted with water and heptane under the conditions of time and temperature specified for condition of use A, as set forth in Table 2 of §176.170(c) of this chapter.

(f) Nylon %12 resins (CAS Reg. No. 25191–04–2) complying with item 13.3 of the table in §177.1500(b), for use as nonfood-contact layers of laminated films and in rigid multilaminate constructions with polypropylene outer layers. Laminate structures with authorized food-contact materials yield no more than 0.15 milligrams of epsilon-caprolactam and 0.04 milligrams of omega-laurolactam per square inch when extracted with 95 percent ethanol at 121 °C (250 °F) for 2 hours.
(g) Polymeric resins that comply with an applicable regulation in this chapter which permits food type and time/temperature conditions to which the container will be exposed, including sterilization processing.

(ii) Adjuvants used in these layers must comply with an applicable regulation that permits food type and time/temperature conditions to which the container will be exposed, including sterilization processing.

(2) Adhesives. The use of adhesives in these containers is optional. Adhesives may be formulated from the following substances, subject to the prescribed limitations:

(i) Any substance suitable for use in formulating adhesives that complies with an applicable regulation of this chapter which permits food type and time/temperature conditions to which the container will be exposed, including sterilization processing.

(ii) Substances complying with §175.105 of this chapter may be used in these constructions, provided they are separated from the interior (food-contact) layer(s) by a functional barrier as discussed under paragraph (a) of this section.

(iii) Maleic anhydride adduct of polypropylene complying with §175.300 of this chapter.

(iv) Polyester-urethane adhesive for use at temperatures not exceeding 121 °C (250 °F) and formulated from the following:

(a) Polyester-polyurethanediol resin prepared by the reaction of a mixture of polybasic acids and polyhydric alcohols listed in §175.300(b)(3)(vii) of this chapter.

(b) Polyester-polyurethanediol resin prepared by the reaction of a mixture of polybasic acids and polyhydric alcohols listed in §175.300(b)(3)(vii) of this chapter and 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098–71–9).

(c) Polyester-urethane cross-linking agent comprising not more than 14 percent weight of the cured adhesive and formulated from 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanurate (CAS Reg. No. 53880–05–0).

(d) Polyester-epoxy-urethane adhesives formulated from the following:

(i) Polyester resin formed by the reaction of polybasic acids and polyhydric alcohols listed in §175.300(b)(3)(vii) of this chapter and 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanurate (CAS Reg. No. 4098–71–9).

(ii) Polyester resin formed by the reaction of azelaic acid and 1,6-hexanediol.

(iii) Epoxy resin listed in §175.300(b)(3)(vii) of this chapter and comprising not more than 5 percent by weight of the cured adhesive.

(iv) Polyester-epoxy-urethane adhesives formulated from the following:

(a) Polyester resin prepared by the reaction of a mixture of polyhydric alcohols listed in §175.300(b)(3)(vii) of this chapter.

(b) Polyester resin prepared by the reaction of a mixture of polyhydric alcohols listed in §175.300(b)(3)(vii) of this chapter and 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098–71–9) and optional trimethoxy silane coupling agents containing amino, epoxy, ether, and/or mercapto groups not to exceed 3 percent by weight of the cured adhesive.

(c) Epoxy resin listed in §175.300(b)(3)(vii) of this chapter and comprising not more than 5 percent by weight of the cured adhesive.

(d) Optional trimethoxy silane curing agents, containing amino, epoxy, ether, or mercapto groups not in excess of 3 percent of the cured adhesive.

(b) Urethane cross-linking agent, comprising not more than 20 percent by weight of the cured adhesive, and formulated from trimethylol propane (CAS Reg. No. 77–99–6) adducts of 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 131–07–3) and/or 1,3-bis(isocyanatomethyl)benzene (CAS Reg. No. 25854–16–4) adduct of trimethylol propane.

(vii) Polyester-polyurethane resin-acid dianhydride adhesives for use at temperatures not to exceed 121 °C (250 °F), in contact only with food Types I,
II. VIA, VIB, VIIB, and VIII as described in Table I of §176.170 of this chapter, and formulated from the following mixture:

(a) Polyesterpolyurethanediol resins prepared by the reaction of a mixture of polybasic acids and polyhydric alcohols listed in §173.300(b)(3)(vii) of this chapter and 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098-71-9). Additionally, dimethylol propionic acid and 1,6-hexanediol may be used alone or in combination as reactants in lieu of a polybasic acid and a polyhydric alcohol.

(b) Urethane cross-linking agent, comprising not more than twelve percent by weight of the cured adhesive, comprising not more than one percent of the cured adhesive.

2. Adducts of isobenzofurandione (CAS Reg. No. 77-99-6) and/or 1,3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098-71-9) and/or 1,3-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098-71-9) and/or 1,3-trimethylcyclohexyl isocyanate (CAS Reg. No. 77-99-6) adducts of 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098-71-9) and/or 1,3-bis(isocyanatomethyl)benzene (CAS Reg. No. 363-48-31).

3. Acid dianhydride formulated from 3a,4,5,7a-tetrahydro-7-methyl-5-(tetrahydro-2,5-dioxo-3-furanyl)-1,3-isobenzofurandione (CAS Reg. No. 73003-90-4), comprising not more than twelve percent by weight of the cured adhesive, comprising not more than one percent of the cured adhesive.

b. Urethane cross-linking agent, comprising not more than twelve percent by weight of the cured adhesive, and formulated from trimethylol propane (CAS Reg. No. 77-99-6) adducts of 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (CAS Reg. No. 4098-71-9) and/or 1,3-bis(isocyanatomethyl)benzene (CAS Reg. No. 363-48-31).

3. Test specifications. These specifications apply only to materials on the food-contact side of a functional barrier, if present. All tests must be performed on containers made under production conditions. Laminated structures submitted to extraction procedures must maintain complete structural integrity (particularly with regard to delamination) throughout the test.

a. Nonvolatile extractives. (a) For use at temperatures not to exceed 121 °C (250 °F): The container interior (food-contact side) shall be extracted with deionized distilled water at 121 °C (250 °F) for 2 hours.

(i) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in paragraphs (c)(2)(i), (c)(2)(ii), (c)(2)(iii), (c)(2)(iv), and (c)(2)(vii) of this section shall not exceed 0.0016 milligram per square centimeter (0.01 milligram per square inch) as determined by a method entitled "Determination of Non-Volatile Chloroform Soluble Residues in Retort Pouch Water Extracts," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(ii) For use at temperatures not to exceed 135 °C (275 °F): The container interior (food-contact side) shall be extracted with deionized distilled water at 135 °C (275 °F) for 1 hour.

(iii) The chloroform-soluble fraction of the total nonvolatile extractives for containers using no adhesive, or adhesives listed in paragraphs (c)(2)(i), (ii), and (iii) of this section shall not exceed 0.0020 milligram per square centimeter (0.013 milligram per square inch) as determined by a method entitled "Determination of Non-volatile Chloroform Soluble Residues in Retort Pouch Water Extracts," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(3)(i)(a)(I) of this section.

(b) Test specifications. These specifications apply only to materials on the food-contact side of a functional barrier, if present. All tests must be performed on containers made under production conditions. Laminated structures submitted to extraction procedures must maintain complete structural integrity (particularly with regard to delamination) throughout the test.

(i) Nonvolatile extractives. (a) For use at temperatures not to exceed 121 °C (250 °F): The container interior (food-contact side) shall be extracted with deionized distilled water at 121 °C (250 °F) for 2 hours.

(ii) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in paragraphs (c)(2)(i), (c)(2)(ii), (c)(2)(iii), (c)(2)(iv), and (c)(2)(vii) of this section shall not exceed 0.0016 milligram per square centimeter (0.01 milligram per square inch) as determined by a method entitled "Determination of Non-Volatile Chloroform Soluble Residues in Retort Pouch Water Extracts," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(iii) For use at temperatures not to exceed 135 °C (275 °F): The container interior (food-contact side) shall be extracted with deionized distilled water at 135 °C (275 °F) for 1 hour.

(iv) The chloroform-soluble fraction of the total nonvolatile extractives for containers using no adhesive, or adhesives listed in paragraphs (c)(2)(i), (ii), and (iii) of this section shall not exceed 0.0020 milligram per square centimeter (0.013 milligram per square inch) as determined by a method entitled "Determination of Non-volatile Chloroform Soluble Residues in Retort Pouch Water Extracts," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(3)(i)(a)(I) of this section.
§ 177.1395 Laminate structures for use at temperatures between 120 °F and 250 °F.

(a) The laminates identified in this section may be safely used at the specified temperatures. These articles are layered structures that are optionally bonded with adhesives. In these articles, the food-contact layer does not function as a barrier to migration of components from non-food-contact layers. The layers may be laminated, extruded, coextruded, or fused.

(b) Laminate structures may be manufactured from:

(1) Polymers and adjuvants complying with §177.1390 of this chapter.

(2) Any polymeric resin listed in these regulations so long as the use of the resin in the structure complies with the conditions of use (food type and time/temperature) specified in the regulation for that resin.

(3) Optional adjuvant substances used in accordance with §174.5 of this chapter.

(4) The following substances in non-food-contact layers only:

<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylene/1,3-phenylene oxy-ethyleneterephthalate/terephthalate copolymer (CAS Reg. No. 87365-98-8) complying with §177.1345.</td>
<td>For use only with polyethylene terephthalate as the food-contact layer, complying with §177.1630 under conditions of use C through G described in table 2 of §176.170(c) of this chapter. Laminate structures, when extracted with 8 percent ethanol at 150 °F for 2 hours shall not yield more than 0.15 milligram of m-phenylenedioxo-0,0'-diethyl isophthalate or cyclic bis(ethylene isophthalate) in excess of 7.8 micrograms/square decimeter (0.5 microgram/square inch) of food-contact surface.</td>
</tr>
<tr>
<td>Nylon 6/12 resins complying with §177.1500(b), item 13.2, of this chapter (CAS Reg. No. 25191-04-2).</td>
<td>For use with nonalcoholic foods at temperatures not to exceed 100 °C (212 °F). Laminate structures with authorized food-contact materials yield no more than 0.15 milligram of epsilon-caprolactam and 0.04 milligram of omega-lauroylactam per square inch when extracted with water at 100 °C (212 °F) for 5 hours.</td>
</tr>
</tbody>
</table>

§ 177.1395 Pouch Water Extracts,' which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(3)(i)(a)(1) of this section.

(3) The chloroform-soluble fraction of the total nonvolatile extractives for containers using adhesives listed in paragraph (c)(2)(vi) of this section shall not exceed 0.008 milligram per square centimeter (0.05 milligram per square inch) as determined by a method entitled, “Determination of Non-volatile Chloroform Soluble Residues in Retort Pouch Water Extracts,” which is incorporated by reference in paragraph (c)(3)(i)(a)(1) of this section.

(ii) Volatiles. Volatile substances employed in the manufacture of high-temperature laminates must be removed to the greatest extent possible in keeping with good manufacturing practice prescribed in §174.5(a) of this chapter.

(d) Nylon 12/aluminum foil high-temperature laminates: Subject to the provisions of this paragraph, containers constructed of nylon 12 laminated to aluminum foil may be safely used at temperatures no greater than 250 °F (121 °C) in contact with all food types except those containing more than 8 percent alcohol.

(1) The container is constructed of aluminum foil to which nylon 12 film is fused. Prior to fusing the nylon 12, the aluminum foil may be optionally precoated with a coating complying with §175.300 of this chapter.

(2) Nylon 12 resin complying with §177.1500 and having an average thickness not to exceed 0.0016 inch (41 microns) may be used as the food-contact surface of the container.

(3) Container test specifications. On exposure to distilled water at 250 °F (121 °C) for 2 hours, extractives from the food-contact side of the nylon 12 multilayered construction shall not exceed 0.05 milligram per square inch (0.0078 milligram per square centimeter) as total nonvolatile extractives.