PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

21 CFR 172.255 Polyacrylamide.

Polyacrylamide containing not more than 0.2 percent of acrylamide monomer may be safely used as a film former in the imprinting of soft-shell gelatin capsules when the amount used is not in excess of the minimum required to produce the intended effect.

21 CFR 172.710 Adjuvants for pesticide use dilutions.

Sodium acrylate and acrylamide copolymer with a minimum average molecular weight of 10,000,000 in which 30 percent of the polymer is comprised of acrylate units and 70 percent acrylamide units, for use as a drift control agent in herbicide formulations applied to crops at a level not to exceed 0.5 ounces of the additive per acre.

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

Subpart A—Polymer Substances and Polymer Adjuvants for Food Treatment

21 CFR 173.5 Acrylate-acrylamide resins.

[§173.10 amended at 46 FR 30494, June 9, 1981]

Acrylate-acrylamide resins may be safely used in food under the following prescribed conditions:

21 CFR 173.5(a)

(a) The additive consists of one of the following:

21 CFR 173.5(a)(1)

(1) Acrylamide-acrylic acid resin (hydrolyzed polyacrylamide) is produced by the polymerization of acrylamide with partial hydrolysis, or by copolymerization of acrylamide and acrylic acid, with the greater part of the polymer being composed of acrylamide units.

21 CFR 173.5(a)(2)

(2) Sodium polyacrylate-acrylamide resin is produced by the polymerization and subsequent hydrolysis of acrylonitrile in a sodium silicate-sodium hydroxide aqueous solution, with the greater part of the polymer being composed of acrylate units.

21 CFR 173.5(b)

(b) The additive contains not more than 0.05 percent of residual monomer calculated as acrylamide.

21 CFR 173.5(c)

(c) The additive is used or intended for use as follows:

21 CFR 173.5(c)(1)

(1) The additive identified in paragraph (a)(1) of this section is used as a flocculent in the clarification of beet sugar juice and liquor or cane sugar juice and liquor or corn starch hydrolyzate in an amount not to exceed 5 parts per million by weight of the juice or 10 parts per million by weight of the liquor or the corn starch hydrolyzate.

21 CFR 173.5(c)(2)

(2) The additive identified in paragraph (a)(2) of this section is used to control organic and mineral scale in beet sugar juice and liquor or cane sugar juice and liquor in an amount not to exceed 2.5 parts per million by weight of the juice or liquor.

21 CFR 173.10 Modified polyacrylamide resin.
Modified polyacrylamide resin may be safely used in food in accordance with the following prescribed conditions:
21 CFR 173.10(a)
(a) The modified polyacrylamide resin is produced by the copolymerization of acrylamide with not more than 5-mole percent b-methacrylyloxyethy-ltrimethylammonium methyl sulfate.
21 CFR 173.10(b)
(b) The modified polyacrylamide resin contains not more than 0.05 percent residual acrylamide.
21 CFR 173.10(c)
(c) The modified polyacrylamide resin is used as a flocculent in the clarification of beet or cane sugar juice in an amount not exceeding 5 parts per million by weight of the juice.
21 CFR 173.10(d)
(d) To assure safe use of the additive, the label and labeling of the additive shall bear, in addition to the other information required by the act, adequate directions to assure use in compliance with paragraph (c) of this section.

21 CFR 173.310 Boiler water additives.

Substances	Limitations
Acrylamide-sodium acrylate resin.....	Contains not more than 0.05 percent by weight of acrylamide monomer.

21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables.

Polyacrylamide.....	Not to exceed 10 parts per million in wash water. Contains not more than 0.2 percent acrylamide monomer. May be used in the washing of fruits and vegetables.

Subpart B—Substances for Use Only as Components of Adhesives
21 CFR 175.105 Adhesives.
N-(1,1-dimethyl-3-oxobutyl) acrylamide

Poly(acrylamide-[2-acrylamide-2-methylpropylsulfonate]-dimethylidiallyl ammonium chloride) sodium salt (CAS Reg. No. 72275-68-4).

Polymers: Homopolymers and copolymers of the following monomers: Acrylamide.	

21 CFR 175.300 Resinous and polymeric coatings.
Vinyl chloride copolymerized with acrylamide and ethylene in such a manner that the finished copolymers have a minimum weight average molecular weight of 30,000 and contain not more than 3.5 weight percent of total polymer units derived from acrylamide; the acrylamide portion may or may not be subsequently partially hydrolyzed.

(xx) Acrylics and their copolymers, as the basic polymer:
Acrylamide with ethylacrylate and/or styrene and/or methacrylic acid, subsequently reacted with formaldehyde and butanol.

21 CFR 175.320 Resinous and polymeric coatings for polyolefin films.

List of Substances	Limitations
(i) Resins and polymers:	
Acrylic acid polymer and its ethyl or methyl esters	
Acrylamide copolymerized with ethyl acrylate and/or styrene and/or methacrylic acid, and the copolymer subsequently reacted with formaldehyde and butanol	
Butadiene-acrylonitrile copolymer	

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS
Subpart B—Substances for Use Only as Components of Paper and Paperboard
21 CFR 176.110 Acrylamide-acrylic acid resins.
Acrylamide-acrylic acid resins may be safely used as components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.
21 CFR 176.110(a)
(a) Acrylamide-acrylic acid resins are produced by the polymerization of acrylamide with partial hydrolysis or by the copolymerization of acrylamide and acrylic acid.
21 CFR 176.110(b)
(b) The acrylamide-acrylic acid resins contain less than 0.2 percent residual monomer.
21 CFR 176.110(c)
(c) The resins are used as adjuvants in the manufacture of paper and paperboard in amounts not to exceed that necessary to accomplish the technical effect and not to exceed 2 percent by weight of the paper or paperboard.

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21 CFR 176.180 Components of paper and paperboard in contact with dry food.

List of substances	Limitations
Polymers: Homopolymers and copolymers of the following monomers:.....	Basic polymer.
Acrylamide.	
Acrylic acid and its methyl, ethyl, butyl, propyl, or octyl esters.	

Subpart B—Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces

21 CFR 177.1010 Acrylic and modified acrylic plastics, semirigid and rigid.

(3) Polymers identified in paragraphs (a)(1) and (2) of this section containing no more than 5 weight-percent of total polymer units derived by copolymerization with one or more of the monomers listed in paragraph (a)(3)(i) and (ii) of this section. Monomers listed in paragraph (a)(3)(ii) of this section are limited to use only in plastic articles intended for repeated use in contact with food.

21 CFR 177.1010(a)(3)(i)

(i) List of minor monomers:

Acrylamide.

Acrylic acid

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

21 CFR 573.120 Acrylamide-acrylic acid resin.

[§573.120 amended at 45 FR 38058, June 6, 1980]

Acrylamide-acrylic acid resin (hydrolized polyacrylamide), only for the purposes of this section as described below, may be safely used in accordance with the following prescribed conditions:

21 CFR 573.120(a)

(a) The additive is produced by polymerization of acrylamide with partial hydrolysis, or by copolymerization of acrylamide and acrylic acid with the greater part of the polymer being composed of acrylamide units.

21 CFR 573.120(b)

(b) The additive meets the following specifications:

21 CFR 573.120(b)(1)

(1) A minimum molecular weight of 3 million.

21 CFR 573.120(b)(2)

(2) Viscosity range: 3,000 to 6,000 centipoises at 77° F in a 1 percent aqueous solution as determined by LVF Brookfield Viscometer or equivalent using a number 6 spindle at 20 r.p.m.

21 CFR 573.120(b)(3)

(3) Residual acrylamide: Not more than 0.05 percent.

21 CFR 573.120(c)

(c) It is used as a thickener and suspending agent in nonmedicated aqueous suspensions intended for addition to animal feeds.

PART 872—DENTAL DEVICES

21 CFR 872.3420 Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive.

[§872.3420 amended at 61 FR 50707, Sept. 27, 1996]

21 CFR 872.3420(a)

(a) Identification. A carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive is a device composed of carboxymethylcellulose sodium and cationic polyacrylamide polymer intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.

21 CFR 872.3420(b)

(b) Classification. Class III.

21 CFR 872.3420(c)

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive that was in commercial distribution before May 28, 1976. Any other carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

21 CFR 872.3480 Polyacrylamide polymer (modified cationic) denture adhesive.

[§872.3480 amended at 61 FR 50707, Sept. 27, 1996]

21 CFR 872.3480(a)

(a) Identification. A polyacrylamide polymer (modified cationic) denture adhesive is a device composed of polyacrylamide polymer (modified cationic) intended to be applied to the base of a denture before the denture is inserted in a patient's mouth to improve denture retention and comfort.

21 CFR 872.3480(b)

(b) Classification. Class III.

21 CFR 872.3480(c)

(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any polyacrylamide polymer (modified cationic) denture

adhesive that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a polyacrylamide polymer (modified cationic) denture adhesive that was in commercial distribution before May 28, 1976. Any other polyacrylamide polymer (modified cationic) denture adhesive shall have an approved PMA or a declared completed PDP in effect before being place in commercial distribution.