§ 186.1797 Sodium sulfate.

(a) Sodium sulfate (Na₂SO₄, CAS Reg. No. 7757–82–6), also known as Glauber’s salt, occurs naturally and exists as colorless crystals or as a fine, white crystalline powder. It is prepared by the neutralization of sulfuric acid with sodium hydroxide.

(b) The ingredient is used as a constituent of paper and paperboard used for food packaging, and cotton and cotton fabric used for dry food packaging.

(c) The ingredient is used at levels not to exceed good manufacturing practice in accordance with §186.1(b)(1).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6086, Jan. 25, 1980]

§ 186.1839 Sorbose.

(a) Sorbose (L-sorbose, sorbinose) (C₆H₁₂O₆, CAS Reg. No. 87–79–6) is an orthorhombic, bisphenoidal crystalline ketohexose. It was originally identified in the juice of mature berries from the mountain ash (Sorbus aucuparia) where it occurs as the result of microbial oxidation of sorbitol. It also occurs naturally in other plants. Sorbose can be synthesized by the catalytic hydrogenation of glucose to D-sorbitol. The resulting sorbitol can be oxidized by Acetobacter xylinum or by Acetobacter suboxydans.

(b) The ingredient is used or intended for indirect food use as a constituent of cotton, cotton fabrics, paper, and paperboard in contact with dry food.

(c) The ingredient migrates to food at levels not to exceed good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

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been shown by adequate scientific data
to be safe for use in human food. Use of
any of these substances in violation of
this section causes the food involved to
be adulterated in violation of the act.

(b) This section includes only a partial
list of substances prohibited from
use in human food, for easy reference
purposes, and is not a complete list of
substances that may not lawfully be
used in human food. No substance may
be used in human food unless it meets
all applicable requirements of the act.

(c) The Commissioner of Food and
Drugs, either on his own initiative or
on behalf of any interested person who
has submitted a petition, may publish
a proposal to establish, amend, or repeal
a regulation under this section on
the basis of new scientific evaluation
or information. Any such petition shall
include an adequate scientific basis to
support the petition, pursuant to part
10 of this chapter, and will be published
for comment if it contains reasonable
grounds.

[42 FR 14659, Mar. 15, 1977, as amended at 54
FR 24899, June 12, 1989]

Subpart B—Prohibited Cattle
Materials

§ 189.5 Prohibited cattle materials.

(a) Definitions. The definitions and inter-
pretations of terms contained in section
201 of the Federal Food, Drug,
and Cosmetic Act (the act) apply to
such terms when used in this part. The
following definitions also apply:

(1) Prohibited cattle materials means
specified risk materials, small intes-
tine of all cattle except as provided in
paragraph (b)(2) of this section, mate-
rial from nonambulatory disabled cat-
tle, material from cattle not inspected
and passed, or mechanically separated
(MS) (Beef). Prohibited cattle mate-
rials do not include the following:

(i) Tallow that contains no more
than 0.15 percent insoluble impurities,
tallow derivatives, hides and hide-de-
rived products, and milk and milk
products, and

(ii) Cattle materials inspected and
passed from a country designated
under paragraph (e) of this section.

(2) Inspected and passed means that
the product has been inspected and
passed for human consumption by the
appropriate regulatory authority, and
at the time it was inspected and
passed, it was found to be not adulter-
ated.

(3) Mechanically Separated (MS)(Beef)
means a meat food product that is fine-
ly comminuted, resulting from the me-
chanical separation and removal of
most of the bone from attached skel-
etal muscle of cattle carcasses and
parts of carcasses that meets the speci-
fications contained in 9 CFR 319.5, the
regulation that prescribes the standard
of identity for MS (Species).

(4) Nonambulatory disabled cattle
means cattle that cannot rise from a
recumbent position or that cannot
walk, including, but not limited to,
those with broken appendages, severed
tendons or ligaments, nerve paralysis,
fractured vertebral column, or meta-
bolic conditions.

(5) Specified risk material means the
brain, skull, eyes, trigeminal ganglia,
spinal cord, vertebral column (exclud-
ing the vertebrae of the tail, the trans-
verse processes of the thoracic and
lumbar vertebrae, and the wings of the
sacrum), and dorsal root ganglia of cat-
tle 30 months and older and the tonsils
and distal ileum of the small intestine
of all cattle.

(6) Tallow means the rendered fat of
beef obtained by pressing or by ap-
plying any other extraction process to
tissues derived directly from discrete
adipose tissue masses or to other car-
cass parts and tissues. Tallow must be
produced from tissues that are not pro-
hibited cattle materials or must con-
tain not more than 0.15 percent insol-
uble impurities as determined by the
method entitled ‘‘Insoluble Impurities’’
(AOCS Official Method Ca 3a-46), Amer-
ican Oil Chemists’ Society (AOCS), 5th
in accordance with 5 U.S.C. 552(a) and 1
CFR part 51, or another method equiva-
 lent in accuracy, precision, and sensi-
tivity to AOCS Official Method Ca 3a-
46. You may obtain copies of the meth-
od from AOCS (http://www.aocs.org)
2211
W. Bradley Ave. Champaign, IL 61821.
Copies may be examined at the Center
for Food Safety and Applied Nutri-
tion’s Library, 5100 Paint Branch
Pkwy., College Park, MD 20740, or at

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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.

(7) Tallow derivative means any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product.

(b) Requirements. (1) No human food shall be manufactured from, processed with, or otherwise contain, prohibited cattle materials.

(2) The small intestine is not considered prohibited cattle material if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine, as measured from the caeco-colic junction and progressing proximally towards the jejunum, or by a procedure that the establishment can demonstrate is equally effective in ensuring complete removal of the distal ileum.

(c) Records. (1) Manufacturers and processors of a human food that is manufactured from, processed with, or otherwise contains, material from cattle must establish and maintain records sufficient to demonstrate that the food is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials.

(2) Records must be retained for 2 years after the date they were created.

(3) Records must be retained at the manufacturing or processing establishment or at a reasonably accessible location.

(4) The maintenance of electronic records is acceptable. Electronic records are considered to be reasonably accessible if they are accessible from an onsite location.

(5) Records required by this section and existing records relevant to compliance with this section must be available to FDA for inspection and copying.

(6) When filing entry with U.S. Customs and Border Protection, the importer of record of a human food manufactured from, processed with, or otherwise containing, cattle material must affirm that the food was manufactured from, processed with, or otherwise contains, cattle material and must affirm that the food was manufactured in accordance with this section. If a human food is manufactured from, processed with, or otherwise contains, cattle material, then the importer of record must, if requested, provide within 5 days records sufficient to demonstrate that the food is not manufactured from, processed with, or does not otherwise contain, prohibited cattle material.

(7) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in §11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

(d) Adulteration. (1) Failure of a manufacturer or processor to operate in compliance with the requirements of paragraphs (b) or (c) of this section renders human food adulterated under section 402(a)(4) of the act.

(2) Human food manufactured from, processed with, or otherwise containing, prohibited cattle materials is unfit for human food and deemed adulterated under section 402(a)(3) of the act.

(3) Food additive status. Prohibited cattle materials for use in human food are food additives subject to section 409 of the act, except when used as dietary ingredients in dietary supplements. The use or intended use of any prohibited cattle material in human food causes the material and the food to be adulterated under section 402(a)(2)(C) of the act, or does not otherwise contain, prohibited cattle material.

(e) Process for designating countries. A country seeking designation must send a written request to the Director, Office of the Center Director, Center for Food Safety and Applied Nutrition,
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Food and Drug Administration, at the address designated in 21 CFR 5.1100. The request shall include information about a country’s bovine spongiform encephalopathy (BSE) case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether specified risk materials, the small intestine of cattle except as provided in paragraph (b)(2) of this section, material from non-ambulatory disabled cattle, or MS (Beef) from cattle from the country should be considered prohibited cattle materials. FDA shall respond in writing to any such request and may impose conditions in granting any such request. A country designation granted by FDA under this paragraph will be subject to future review by FDA, and may be revoked if FDA determines that it is no longer appropriate.


Subpart C—Substances Generally Prohibited From Direct Addition or Use as Human Food


§ 189.110 Calamus and its derivatives.

(a) Calamus is the dried rhizome of Acorus calamus L. It has been used as a flavoring compound, especially as the oil or extract.

(b) Food containing any added calamus, oil of calamus, or extract of calamus is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of May 9, 1968 (33 FR 6967).

(c) The analytical method used for detecting oil of calamus (β-asarone) is in the “Journal of the Association of Official Analytical Chemists,” Volume 56, (Number 5), pages 1281 to 1283, September 1973, which is incorporated by reference. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, also from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection 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.

[42 FR 14659, Mar. 15, 1977, as amended at 47 FR 11855, Mar. 19, 1982; 54 FR 24899, June 12, 1989]

§ 189.113 Cinnamyl anthranilate.

(a) The food additive cinnamyl anthranilate (C16H15NO2, CAS Reg. No. 87–29–6) is the ester of cinnamyl alcohol and anthranilic acid. Cinnamyl anthranilate is a synthetic chemical that has not been identified in natural products at levels detectable by available methodology. It has been used as a flavoring agent in food.

(b) Food containing any added cinnamyl anthranilate is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of October 23, 1985.

[50 FR 42932, Oct. 23, 1985]

§ 189.120 Cobaltous salts and its derivatives.

(a) Cobaltous salts are the chemicals, CoC4H6O4, CoCl2, and CoSO4. They have been used in fermented malt beverages as a foam stabilizer and to prevent “gushing.”

(b) Food containing any added cobaltous salts is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of August 12, 1966 (31 FR 8788).

§ 189.130 Coumarin.

(a) Coumarin is the chemical 1,2-benzopyrone, C9H6O2. It is found in tonka beans and extract of tonka beans, among other natural sources, and is also synthesized. It has been used as a flavoring compound.

(b) Food containing any added coumarin as such or as a constituent of tonka beans or tonka extract is deemed to be adulterated under the act, based
§ 189.135 Cyclamate and its derivatives.

(a) Calcium, sodium, magnesium and potassium salts of cyclohexane sulfamic acid, \((C_6H_{12}NO_3S)\)\(_2\)Ca, \((C_6H_{12}NO_3S)\)Na, \((C_6H_{12}NO_3S)\)Mg, and \((C_6H_{12}NO_3S)\)K. Cyclamates are synthetic chemicals having a sweet taste 30 to 40 times that of sucrose, are not found in natural products at levels detectable by the official methodology, and have been used as artificial sweeteners.

(b) Food containing any added or detectable level of cyclamate is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of October 21, 1969 (34 FR 17063).

(c) The analytical methods used for detecting cyclamate in food are in sections 20.162–20.172 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined 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.


§ 189.140 Diethylpyrocarbonate (DEPC).

(a) Diethylpyrocarbonate is the chemical pyrocarbonic acid diethyl ester, \(C_6H_{10}O_5\). It is a synthetic chemical not found in natural products at levels detectable by available methodology and has been used as a ferment inhibitor in alcoholic and nonalcoholic beverages.

(b) Food containing any added or detectable level of DEPC is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of August 2, 1972 (37 FR 15426).

§ 189.145 Dulcin.

(a) Dulcin is the chemical 4-ethoxyphenylurea, \(C_9H_{12}N_2O_2\). It is a synthetic chemical having a sweet taste about 250 times that of sucrose, is not found in natural products at levels detectable by the official methodology, and has been proposed for use as an artificial sweetener.

(b) Food containing any added or detectable level of dulcin is deemed to be adulterated in violation of the act, based upon an order published in the FEDERAL REGISTER of January 19, 1950 (15 FR 321).

(c) The analytical methods used for detecting dulcin in food are in sections 20.173–20.176 of the “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined 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.

§ 189.155 Monochloroacetic acid.

(a) Monochloroacetic acid is the chemical chloroacetic acid, \(\text{C}_2\text{H}_3\text{ClO}_2\). It is a synthetic chemical not found in natural products, and has been proposed as a preservative in alcoholic and nonalcoholic beverages. Monochloroacetic acid is permitted in food package adhesives with an accepted migration level up to 10 parts per billion (ppb) under § 175.105 of this chapter. The official methods do not detect monochloroacetic acid at the 10 ppb level.

(b) Food containing any added or detectable level of monochloroacetic acid is deemed to be adulterated in violation of the act based upon trade correspondence dated December 29, 1941 (TC–377).

(c) The analytical methods used for detecting monochloroacetic acid in food are in sections 20.067–20.072 of the “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined 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.


§ 189.165 Nordihydroguaiaretic acid (NDGA).

(a) Nordihydroguaiaretic acid is the chemical 4,4′-(2,3-dimethyltetramethylene) dipyrocatechol, \(\text{C}_{18}\text{H}_{22}\text{O}_4\). It occurs naturally in the resinous exudates of certain plants. The commercial product, which is synthesized, has been used as an antioxidant in foods.

(b) Food containing any added NDGA is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of January 19, 1950 (15 FR 321).

(c) The analytical methods used for detecting NDGA in food are in sections 20.177–20.181 of the “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined 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.


§ 189.175 P–4000.

(a) P–4000 is the chemical 5-nitro-2-n-propoxyaniline, \(\text{C}_9\text{H}_{12}\text{N}_2\text{O}_3\). It is a synthetic chemical having a sweet taste about 4000 times that of sucrose, is not found in natural products at levels detectable by the official methodology, and has been proposed for use as an artificial sweetener.

(b) Food containing any added or detectable level of P–4000 is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of January 19, 1950 (15 FR 321).

(c) The analytical methods used for detecting P–4000 in food are in sections 20.177–20.181 of the “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined 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.


§ 189.180 Safrole.

(a) Safrole is the chemical 4-allyl-1,2-methylenedioxy-benzene, \(\text{C}_{10}\text{H}_{10}\text{O}_2\). It is a natural constituent of the sassafras
§ 189.190 Thiourea.

(a) Thiourea is the chemical thiocarbamide, CH₄N₂S. It is a synthetic chemical, is not found in natural products at levels detectable by the official methodology, and has been proposed as an antmycotic for use in dipping citrus.

(b) Food containing any added or detectable level of thiourea is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of April 7, 1967 (32 FR 5675).


§ 189.191 Chlorofluorocarbon propellants.

The use of chlorofluorocarbons in human food as propellants in self-presurized containers is prohibited as provided by §2.125 of this chapter.

[43 FR 11317, Mar. 17, 1978]
(60 FR 31109, June 27, 1995)

§ 189.250 Mercaptoimidazoline and 2-mercaptoimidazoline.

(a) Mercaptoimidazoline and 2-mercaptoimidazoline both have the molecular formula C₃H₆N₂S. They are synthetic chemicals not found in natural products and have been used in the production of rubber articles that may come into contact with food.

(b) Food containing any added or detectable levels of these substances is deemed to be adulterated in violation of the act based upon an order published in the Federal Register of October 9, 1987 (52 FR 33929).

§ 189.280 4,4′-Methylenebis (2-chloroaniline).

(a) 4,4′-Methylenebis (2-chloroaniline) has the molecular formula C₁₃H₁₂Cl₂N₂. It is a synthetic chemical not found in natural products and has been used as a polyurethane curing agent and as a component of food packaging adhesives and polyurethane resins.

(b) Food containing any added or detectable level of this substance is deemed to be adulterated in violation of the act based upon an order published in the Federal Register of December 2, 1969 (34 FR 19073).

§ 189.300 Hydrogenated 4,4′-isopropylidene-diphenolphosphate ester resins.

(a) Hydrogenated 4,4′-isopropylidene-diphenolphosphate ester resins are the condensation product of 1 mole of triphenyl phosphate and 1.5 moles of hydrogenated 4,4′-isopropylidene-diphenol such that the finished resins have a molecular weight in the range of 2,400 to 3,000. They are synthetic chemicals not found in natural products and have been used as antioxidants and as stabilizers in vinyl chloride polymer resins when such polymer resins are used in the manufacture of rigid vinyl chloride polymer bottles.

(b) Food containing any added or detectable levels of these substances is deemed to be adulterated and in violation of the Federal Food, Drug, and Cosmetic Act, based upon an order published in the Federal Register of September 9, 1987 (52 FR 33929).

(54 FR 7188, Feb. 17, 1989)

§ 189.301 Tin-coated lead foil capsules for wine bottles.

(a) Tin-coated lead foil is composed of a lead foil coated on one or both sides with a thin layer of tin. Tin-coated lead foil has been used as a capsule (i.e., as a covering applied over the cork and neck areas) on wine bottles to prevent insect infestation, as a barrier to oxygen, and for decorative purposes. Information received by the Food and Drug Administration establishes that the use of such a capsule on wine bottles may reasonably be expected to result in lead becoming a component of the wine.

(b) The capping of any bottles of wine after February 8, 1996, with a tin-coated lead foil capsule renders the wine adulterated and in violation of section 402(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act because lead from the capsule, which is an unsafe food additive within the meaning of section 409 of the act, may reasonably be expected to become a component of the wine.

(61 FR 4820, Feb. 8, 1996)

PART 190—DIETARY SUPPLEMENTS

Subpart A [Reserved]

Subpart B—New Dietary Ingredient Notification

Sec.
190.6 Requirement for premarket notification.

[Authority: Secs. 201(ff), 301, 402, 413, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff), 331, 402, 413, 371).]

[82 FR 49891, Sept. 23, 1997, unless otherwise noted.]

Editorial Note: Nomenclature changes to part 190 appear at 66 FR 56035, Nov. 6, 2001.

Subpart A [Reserved]