shall be furnished in the form specified in §§171.1 and 171.100 for submitting petitions.


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

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§ 172.5 General provisions for direct food additives.

(a) Regulations prescribing conditions under which food additive substances may be safely used predicate usage under conditions of good manufacturing practice. For the purposes of this part, good manufacturing practice shall be defined to include the following restrictions.

(1) The quantity of the substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritive, or other technical effect in food.

(b) The existence of a regulation prescribing safe conditions of use for a food additive shall not be construed to relieve the use of the substance from
§ 172.105  Anoxomer.

Anoxomer as identified in this section may be safely used in accordance with the following conditions:

(a) Anoxomer is 1,4-benzenediol, 2-(1,1-dimethylethyl)-polymer with diethenylbenzene, 4-(1,1-dimethylethyl)phenol, 4-methoxyphenol, 4′-(1-methylene)bis(phenol) and 4-methylphenol (CAS Reg. No. 60837–57–2) prepared by condensation polymerization of divinylbenzene (m- and p-) with tert-butylhydroquinone, tert-butylphenol, hydroxyanisole, p-cresol and 4,4′-isopropylidenediphenol.

(b) The polymeric antioxidant meets the following specifications:

(1) Polymer, not less than 98.0 percent as determined by an ultraviolet method entitled “Ultraviolet Assay,” 1982, 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, 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.

(2) Molecular weight: Total monomers, dimers and trimers below 500 not more than 1 percent as determined by a method entitled “Low Molecular Weight Anoxomer Analysis,” 1982, 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, 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.

(3) Phenol content: Not less than 3.2 milliequivalent/gram and not more than 3.8 milliequivalent/gram as determined by a method entitled “Total Phenols,” 1982, 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, 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.

(4) Heavy metals as lead (as Pb), not more than 10 parts per million. Arsenic (as As), not more than 3 parts per million. Mercury (as Hg), not more than 1 part per million.

(c) Anoxomer may be safely used as an antioxidant in food at a level of not more than 5,000 parts per million based on fat and oil content of the food.

[48 FR 18798, Apr. 26, 1983, as amended at 54 FR 24896, June 12, 1989]

§ 172.110  BHA.

The food additive BHA (butylated hydroxyanisole) alone or in combination with other antioxidants permitted in food for human consumption in this subpart B may be safely used in or on specified foods, as follows:

(a) The BHA meets the following specification:

Assay (total BHA), 98.5 percent minimum. Melting point 48 °C minimum.

(b) The BHA is used alone or in combination with BHT, as an antioxidant in foods, as follows:

<table>
<thead>
<tr>
<th>Food</th>
<th>Limitations (total BHA and BHT) parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dehydrated potato shreds</td>
<td>50</td>
</tr>
<tr>
<td>Active dry yeast</td>
<td>1,100</td>
</tr>
<tr>
<td>Beverages and desserts prepared from dry mixes</td>
<td>12</td>
</tr>
<tr>
<td>Dry breakfast cereals</td>
<td>50</td>
</tr>
<tr>
<td>Dry diced glazed fruit</td>
<td>152</td>
</tr>
<tr>
<td>Dry mixes for beverages and desserts</td>
<td>190</td>
</tr>
<tr>
<td>Emulsion stabilizers for shortenings</td>
<td>200</td>
</tr>
<tr>
<td>Potato flakes</td>
<td>50</td>
</tr>
</tbody>
</table>
Food and Drug Administration, HHS

§ 172.120  Calcium disodium EDTA.

The food additive calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate) may be safely used in designated foods for the purposes and in accordance with the conditions prescribed, as follows:

(a) The additive contains a minimum of 99 percent by weight of either the dihydrate \( \text{Ca} \cdot \text{Na}_{2} \cdot 4 \cdot \text{H}_{2} \text{O} \) or the trihydrate \( \text{Ca} \cdot \text{Na}_{2} \cdot 5 \cdot \text{H}_{2} \text{O} \), or any mixture of the two.

(b) It is used or intended for use as follows:

1. In the following foods at not to exceed the levels prescribed, calculated as the anhydrous compound:

<table>
<thead>
<tr>
<th>Food</th>
<th>Limitation (parts per million)</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cabbage, pickled</td>
<td>220</td>
<td>Promote color, flavor, and texture retention.</td>
</tr>
<tr>
<td>Canned carbonated soft drinks.</td>
<td>33</td>
<td>Promote flavor retention.</td>
</tr>
<tr>
<td>Canned white potatoes</td>
<td>110</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Clams (cooked canned)</td>
<td>340</td>
<td>Retard struvite formation; promote color retention.</td>
</tr>
<tr>
<td>Distilled alcoholic beverages.</td>
<td>25</td>
<td>Promote stability of color, flavor, and/or product clarity.</td>
</tr>
<tr>
<td>Dressings, nonstandardized.</td>
<td>75</td>
<td>Preservative.</td>
</tr>
<tr>
<td>Dried lima beans</td>
<td>310</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Egg product that is hard-cooked and consists, in a cylindrical shape, of egg white with an inner core of egg yolk.</td>
<td>200</td>
<td>Preservative.</td>
</tr>
<tr>
<td>Fermented malt beverages.</td>
<td>25</td>
<td>Antigushing agent.</td>
</tr>
<tr>
<td>French dressing</td>
<td>75</td>
<td>Preservative.</td>
</tr>
<tr>
<td>Legumes (all cooked canned, other than dried lima beans, pink beans, and red beans).</td>
<td>365</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Mayonnaise</td>
<td>75</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Mushrooms (cooked canned).</td>
<td>200</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Oleomargarine</td>
<td>75</td>
<td>Preservative.</td>
</tr>
<tr>
<td>Pecan pie filling</td>
<td>100</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Pink beans (cooked canned).</td>
<td>165</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Processed dry pinto beans.</td>
<td>800</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Red beans (cooked canned).</td>
<td>165</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Salad dressing</td>
<td>75</td>
<td>Preservative.</td>
</tr>
<tr>
<td>Sandwich spread</td>
<td>100</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Sauces</td>
<td>75</td>
<td>Do.</td>
</tr>
</tbody>
</table>

(c) To assure safe use of the additive:

(1) The label of any market package of the additive shall bear, in addition to the other information required by the Act, the name of the additive.

(2) When the additive is marketed in a suitable carrier, in addition to meeting the requirement of paragraph (c)(1) of this section, the label shall declare the percentage of the additive in the mixture.
§ 172.130 Dehydroacetic acid.

The food additive dehydroacetic acid and/or its sodium salt may be safely used in accordance with the following prescribed conditions:

(a) The food additive meets the following specifications:

Dehydroacetic acid: Melting point, 109 °C–111 °C; assay, minimum 98 percent (dry basis).

Sodium salt of dehydroacetic acid: Assay, minimum 98 percent (dry basis).

(b) It is used or intended for use as a preservative for cut or peeled squash, and is so used that no more than 65 parts per million expressed as dehydroacetic acid remains in or on the prepared squash.

(c) The label or labeling of any package of the additive intended for use in food shall bear adequate directions for use to insure compliance with this section.

§ 172.133 Dimethyl dicarbonate.

Dimethyl dicarbonate (CAS Reg. No. 4525–33–1) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive meets the following specifications:

(1) The additive has a purity of not less than 99.8 percent as determined by the following titration method:

**PRINCIPLES OF METHOD**

Dimethyl dicarbonate (DMDC) is mixed with excess diisobutylamine with which it reacts quantitatively. The excess amine is backtitrated with acid.

**APPARATUS**

- 250-milliliter (mL) Beaker
- 100-mL Graduate cylinder
- 25-mL Pipette
- 10-mL Burette (automatic, e.g., Metrohm burette)
- Stirrer
- Device for potentiometric titration
- Reference electrode
- Glass electrode

**REAGENTS**

- Acetone, analytical-grade
- Solution of 1 N diisobutylamine in chlorobenzene, distilled
- 1 N Acetic Acid

**PROCEDURE**

Accurately weigh in about 2 grams of the sample (W) and dissolve in 100 mL acetone. Add accurately 25 mL of the 1 N diisobutylamine solution by pipette and allow to stand for 5 minutes. Subsequently, titrate the reaction mixture potentiometrically with 1 N hydrochloric acid (consumption=α mL) while stirring. For determining the blank consumption, carry out the analysis without a sample (consumption=β mL).
CALCULATION

\[
\frac{(b - a) \times 13.4}{W} = \% \text{ DMDC}
\]

NOTE: For adding the disobutylamine solution, always use the same pipette and wait for a further three drops to fall when the flow has stopped.

(2) The additive contains not more than 2,000 ppm (0.2 percent) dimethyl carbonate as determined by a method entitled “Gas Chromatography Method for Dimethyl Carbonate Impurity in Dimethyl Dicarbonate,” which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), 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.

(b) The additive is used or intended for use as a microbial control agent in the following beverages under normal circumstances of bottling, canning, or other forms of final packaging, where the viable microbial load has been reduced to 500 microorganisms per milliliter or less by current good manufacturing practices such as heat treatment, filtration, or other technologies prior to the use of dimethyl dicarbonate:

(1) In wine, dealcoholized wine, and low alcohol wine in an amount not to exceed 200 parts per million.

(2) In ready-to-drink teas in an amount not to exceed 250 parts per million.

(3) In carbonated or noncarbonated, nonjuice-containing (less than or equal to 1 percent juice), flavored or unflavored beverages containing added electrolytes (5–20 milliequivalents/liter sodium ion (Na+) and 3–7 milliequivalents/liter potassium ion (K+)) in an amount not to exceed 250 parts per million.

(4) In carbonated, dilute beverages containing juice, fruit flavor, or both, with juice content not to exceed 50 percent, in an amount not to exceed 250 parts per million.

(c) To ensure the safe use of the food additive, the label of the package containing the additive shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The name of the additive “dimethyl dicarbonate.”

(2) The intended use of the additive.

(3) Adequate directions for use to ensure compliance with this section.

§ 172.135 Disodium EDTA.

The food additive disodium EDTA (disodium ethylenediaminetetraacetate) may be safely used in designated foods for the purposes and in accordance with the following prescribed conditions:

(a) The additive contains a minimum of 99 percent disodium ethylenediaminetetraacetate dihydrate (C10H14O8N2Na2·2H2O).

(b) It is used or intended for use as follows:

(1) Alone, in the following foods at not to exceed the levels prescribed, calculated as anhydrous calcium disodium EDTA:

<table>
<thead>
<tr>
<th>Food</th>
<th>Limitation (parts per million)</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aqueous multivitamin preparations.</td>
<td>150</td>
<td>With iron salts as a stabilizer for vitamin B12 in liquid multivitamin preparations.</td>
</tr>
<tr>
<td>Canned black-eyed peas</td>
<td>145</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Canned kidney beans</td>
<td>165</td>
<td>Preservative.</td>
</tr>
<tr>
<td>Canned strawberry pie filling</td>
<td>500</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Cooked sausage</td>
<td>36</td>
<td>As a cure accelerant with sodium ascorbate or ascorbic acid.</td>
</tr>
<tr>
<td>Dressings, nonstandardized</td>
<td>75</td>
<td>Preservative.</td>
</tr>
<tr>
<td>French dressing</td>
<td>75</td>
<td>Do.</td>
</tr>
<tr>
<td>Frozen white potatoes</td>
<td>100</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Gelatin fish balls or patties in packing medium</td>
<td>150</td>
<td>Inhibit discoloration.</td>
</tr>
<tr>
<td>Legumes (all cooked canned, other than black-eyed peas)</td>
<td>165</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Mayonnaise</td>
<td>75</td>
<td>Preservative.</td>
</tr>
</tbody>
</table>

§ 172.135 Disodium EDTA.

The food additive disodium EDTA (disodium ethylenediaminetetraacetate) may be safely used in designated foods for the purposes and in accordance with the following prescribed conditions:

(a) The additive contains a minimum of 99 percent disodium ethylenediaminetetraacetate dihydrate (C10H14O8N2Na2·2H2O).

(b) It is used or intended for use as follows:

(1) Alone, in the following foods at not to exceed the levels prescribed, calculated as anhydrous calcium disodium EDTA:

<table>
<thead>
<tr>
<th>Food</th>
<th>Limitation (parts per million)</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aqueous multivitamin preparations.</td>
<td>150</td>
<td>With iron salts as a stabilizer for vitamin B12 in liquid multivitamin preparations.</td>
</tr>
<tr>
<td>Canned black-eyed peas</td>
<td>145</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Canned kidney beans</td>
<td>165</td>
<td>Preservative.</td>
</tr>
<tr>
<td>Canned strawberry pie filling</td>
<td>500</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Cooked sausage</td>
<td>36</td>
<td>As a cure accelerant with sodium ascorbate or ascorbic acid.</td>
</tr>
<tr>
<td>Dressings, nonstandardized</td>
<td>75</td>
<td>Preservative.</td>
</tr>
<tr>
<td>French dressing</td>
<td>75</td>
<td>Do.</td>
</tr>
<tr>
<td>Frozen white potatoes</td>
<td>100</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Gelatin fish balls or patties in packing medium</td>
<td>150</td>
<td>Inhibit discoloration.</td>
</tr>
<tr>
<td>Legumes (all cooked canned, other than black-eyed peas)</td>
<td>165</td>
<td>Promote color retention.</td>
</tr>
<tr>
<td>Mayonnaise</td>
<td>75</td>
<td>Preservative.</td>
</tr>
</tbody>
</table>
§ 172.140 Ethoxyquin.

(a) Ethoxyquin (1,2-dihydro-6-ethoxy-2,2,4-trimethyquinoline) may be safely used as an antioxidant for preservation of color in the production of chili powder, paprika, and ground chili at levels not in excess of 100 parts per million.

(b) In order to provide for the safe use of the additive in feed prepared in accordance with §§573.380 and 573.400 of this chapter, tolerances are established for residues of ethoxyquin in or on edible products of animals as follows:

- 5 parts per million in or on the uncooked fat of meat from animals except poultry.
- 3 parts per million in or on the uncooked liver and fat of poultry.
- 0.5 part per million in or on the uncooked muscle meat of animals.
- 0.5 part per million in poultry eggs.
- Zero in milk.

§ 172.145 Heptylparaben.

(a) The food additive heptylparaben is the chemical n-heptyl p-hydroxybenzoate.

(b) It may be safely used to inhibit microbiological spoilage in accordance with the following prescribed conditions:

- In fermented malt beverages in amounts not to exceed 12 parts per million.
- In noncarbonated soft drinks and fruit-based beverages in amounts not to exceed 20 parts per million, when standards of identity established under section 401 of the Act (21 U.S.C. 341) do not preclude such use.

§ 172.150 4-Hydroxymethyl-2,6-di-tert-butylphenol.

The food additive 4-hydroxymethyl-2,6-di-tert-butylphenol may be safely used in food in accordance with the following prescribed conditions:

(a) The additive has a solidification point of 140 °C–141 °C.

(b) The additive is used as an antioxidant alone or in combination with other permitted antioxidants.

(c) The total amount of all antioxidants added to such food shall not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.
§ 172.155 Natamycin (pimaricin).

(a) Natamycin (CAS Reg. No. 7681–93–8), also known as pimaricin, is a polyene macrolide antimycotic substance possessing an empirical formula of $\text{C}_{33}\text{H}_{47}\text{NO}_{13}$ and a molecular weight of 665.7.

(b) The additive shall conform to the following specifications:

Purity: 97 percent ± 2 percent on an anhydrous basis.

Arsenic: Not more than 1 part per million.

Heavy metals (as Pb): Not more than 20 parts per million.

(c) The additive may be applied on cheese, as an antimycotic, in amounts not to exceed 20 milligrams per kilogram (20 parts per million) in the finished product as determined by International Dairy Federation (IDF) Standard 140A:1992, “Cheese and Cheese Rind-Determination of Natamycin Content-Method by Molecular Absorption Spectrometry and by High-Performance Liquid Chromatography,” which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Product Policy (HFS–206), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or 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.


§ 172.165 Quaternary ammonium chloride combination.

The food additive, quaternary ammonium chloride combination, may be safely used in food in accordance with the following conditions:

(a) The additive contains the following compounds: $n$-dodecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 122–18–9); $n$-octadecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 139–08–2); $n$-tetradecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 27479–29–4).

(b) The additive meets the following specifications: pH (5 percent active solution) 7.0–8.0; total amines, maximum 1 percent as combined free amines and amine hydrochlorides.

(c) The additive is used as an antimicrobial agent, as defined in §170.3(o)(2) of this chapter, in raw sugar cane juice. It is added prior to clarification when further processing of the sugar cane juice must be delayed.

(d) The additive is applied to the sugar juice in the following quantities, based on the weight of the raw cane:

<table>
<thead>
<tr>
<th>Component</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>$n$-Dodecyl dimethyl benzyl ammonium chloride</td>
<td>0.25–1.0</td>
</tr>
<tr>
<td>$n$-Dodecyl dimethyl ethylbenzyl ammonium chloride</td>
<td>3.4–13.5</td>
</tr>
<tr>
<td>$n$-Hexadecyl dimethyl benzyl ammonium chloride</td>
<td>1.5–6.0</td>
</tr>
<tr>
<td>$n$-Octadecyl dimethyl benzyl ammonium chloride</td>
<td>0.25–1.0</td>
</tr>
<tr>
<td>$n$-Tetradecyl dimethyl benzyl ammonium chloride</td>
<td>3.0–12.0</td>
</tr>
<tr>
<td>$n$-Tetradecyl dimethyl ethylbenzyl ammonium chloride</td>
<td>1.6–6.5</td>
</tr>
</tbody>
</table>

[50 FR 3890, Jan. 29, 1985]

§ 172.167 Silver nitrate and hydrogen peroxide solution.

An aqueous solution containing a mixture of silver nitrate and hydrogen peroxide may be safely used in accordance with the following prescribed conditions:

(a) The additive is used as a antimicrobial agent in bottled water.
(b) Hydrogen peroxide meets the specifications of the “Food Chemicals Codex,” 6th ed. (2008), pp. 463 and 464, which is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address http://www.usp.org). Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2163, 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.

(c) The amount of silver added will not exceed 17 micrograms per kilogram in the treated bottled water, and the amount of hydrogen peroxide will not exceed 23 milligrams per kilogram in the treated bottled water. Analyses for silver and hydrogen peroxide shall be conducted on samples of treated bottled water at the site of bottling, using samples of the water intended for treatment for the blank determination.


(2) The amount of hydrogen peroxide in the treated bottled water is determined using a Hydrogen Peroxide Test Kit from the HACH Co., or equivalent. The manual from the Hydrogen Peroxide Test Kit, Model HYP–1, Catalog Number 22917–00, 1991, is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of the test kit manual from the HACH Co., P.O. Box 389, Loveland CO, 80539 (1–800–227–4224), Model HYP–1, Catalog Number 22917–00. Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2163, 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.

(e) Substances generally recognized as safe in or on food may be used to stabilize the additive to ensure that the additive will perform its intended technical effect.

(f) The additive may not be added to bottled water that has been filtered or is intended to be filtered through a silver-containing water filter.

(g) Bottled water must meet the quality standards for bottled water in §165.110(b)(2) through (b)(5) of this chapter, including the limits specified for total silver and nitrate, unless the water bears a label statement of substandard quality, as provided for under §165.110(c) of this chapter.

[74 FR 11478, Mar. 18, 2009]

§ 172.170 Sodium nitrate.

The food additive sodium nitrate may be safely used in or on specified foods in accordance with the following prescribed conditions:

(a) It is used or intended for use as follows:

(1) As a preservative and color fixative, with or without sodium nitrite, in smoked, cured sablefish, smoked, cured salmon, and smoked, cured shad, so that the level of sodium nitrate does not exceed 500 parts per million and the level of sodium nitrite does not exceed 200 parts per million in the finished product.

(2) As a preservative and color fixative, with or without sodium nitrite, in meat-curing preparations for the home curing of meat and meat products (including poultry and wild game), with directions for use which limit the amount of sodium nitrate to not more than 500 parts per million in the finished meat product and the amount of sodium nitrite to not more than 200 parts per million in the finished meat product.

(b) To assure safe use of the additive, in addition to the other information required by the Act:
§ 172.177  Sodium nitrite used in processing smoked chub.

The food additive sodium nitrite may be safely used in combination with salt (NaCl) to aid in inhibiting the outgrowth and toxin formation from *Clostridium botulinum* type E in the commercial processing of smoked chub in accordance with the following prescribed conditions:

(a) All fish in smoking establishments shall be clean and wholesome and shall be expeditiously processed, packed, and stored under adequate sanitary conditions in accordance with good manufacturing practice.

(b) The brining procedure is controlled in such a manner that the water phase portion of the edible portion of the finished smoked product has a salt (NaCl) content of not less than 3.5 percent, as measured in the loin muscle, and the sodium nitrite content of the edible portion of the finished smoked product is not less than 100 parts per million and not greater than 200 parts per million, as measured in the loin muscle.

(c) Smoked chub shall be heated by a controlled heat process which provides a monitoring system positioned in as many strategic locations in the smokehouse as necessary to assure a continuous temperature throughout each fish of at least 160 °F for a minimum of 30 minutes.

(d) The finished product shall be cooled to a temperature of 50 °F or below within 3 hours after smoking and further cooled to a temperature of 38 °F or below within 12 hours after smoking. A temperature of 38 °F or below shall be maintained during all subsequent

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(1) The label of the additive or of a mixture containing the additive shall bear:
   (i) The name of the additive.
   (ii) A statement of the concentration of the additive in any mixture.

(2) If in a retail package intended for household use, the label and labeling of the additive, or of a mixture containing the additive, shall bear adequate directions for use to provide a final food product which complies with the limitations prescribed in paragraph (a) of this section.

(3) If in a retail package intended for household use, the label of the additive or of a mixture containing the additive, shall bear the statement “Keep out of the reach of children”.

§ 172.175  Sodium nitrite.

The food additive sodium nitrite may be safely used in or on specified foods in accordance with the following prescribed conditions:

(a) It is used or intended for use as follows:

(1) As a color fixative in smoked cured tunafish products so that the level of sodium nitrite does not exceed 10 parts per million (0.001 percent) in the finished product.

(2) As a preservative and color fixative, with or without sodium nitrate, in smoked, cured sablefish, smoked, cured salmon, and smoked, cured shad so that the level of sodium nitrite does not exceed 200 parts per million and the level of sodium nitrate does not exceed 500 parts per million in the finished product.

(3) As a preservative and color fixative, with sodium nitrate, in meat-curing preparations for the home curing of meat and meat products (including poultry and wild game), with directions for use which limit the amount of sodium nitrite to not more than 200 parts per million in the finished meat product.

(b) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive or of a mixture containing the additive shall bear:
   (i) The name of the additive.
   (ii) A statement of the concentration of the additive in any mixture.

(2) If in a retail package intended for household use, the label and labeling of the additive, or of a mixture containing the additive, shall bear adequate directions for use to provide a final food product which complies with the limitations prescribed in paragraph (a) of this section.

(3) If in a retail package intended for household use, the label of the additive, or of a mixture containing the additive, shall bear the statement “Keep out of the reach of children”.

§ 172.177  Sodium nitrite used in processing smoked chub.

The food additive sodium nitrite may be safely used in combination with salt (NaCl) to aid in inhibiting the outgrowth and toxin formation from *Clostridium botulinum* type E in the commercial processing of smoked chub in accordance with the following prescribed conditions:

(a) All fish in smoking establishments shall be clean and wholesome and shall be expeditiously processed, packed, and stored under adequate sanitary conditions in accordance with good manufacturing practice.

(b) The brining procedure is controlled in such a manner that the water phase portion of the edible portion of the finished smoked product has a salt (NaCl) content of not less than 3.5 percent, as measured in the loin muscle, and the sodium nitrite content of the edible portion of the finished smoked product is not less than 100 parts per million and not greater than 200 parts per million, as measured in the loin muscle.

(c) Smoked chub shall be heated by a controlled heat process which provides a monitoring system positioned in as many strategic locations in the smokehouse as necessary to assure a continuous temperature throughout each fish of at least 160 °F for a minimum of 30 minutes.

(d) The finished product shall be cooled to a temperature of 50 °F or below within 3 hours after smoking and further cooled to a temperature of 38 °F or below within 12 hours after smoking. A temperature of 38 °F or below shall be maintained during all subsequent
storage and distribution. All shipping containers, retail packages, and shipping records shall indicate with appropriate notice the perishable nature of the product and specify that the product shall be held under refrigeration (38 °F or below) until consumed.

(e) To assure safe use of the additive:
(1) The label and labeling of the additive container shall bear, in addition to the other information required by the Act, the name of the additive.
(2) The label or labeling of the additive container shall bear adequate directions to assure use in compliance with the provisions of this section.

§ 172.180 Stannous chloride.
The food additive stannous chloride may be safely used for color retention in asparagus packed in glass, with lids lined with an inert material, in an amount not to exceed 20 parts per million calculated as tin (Sn).

§ 172.185 TBHQ.
The food additive TBHQ, which is the chemical 2-(1,1-dimethylethyl)-1,4-benzenediol (Chemical Abstracts Service Registry Number 1948–33–0), also known as tertiary butylhydroquinone, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive has a melting point of 126.5 °C–128.5 °C.
(b) It is used as an antioxidant alone or in combination with other permitted antioxidants.
(c) The total antioxidant content of a food containing the additive will not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.

Subpart C—Coatings, Films and Related Substances

§ 172.210 Coatings on fresh citrus fruit.
Coatings may be applied to fresh citrus fruit for protection of the fruit in accordance with the following conditions:

(a) The coating is applied in the minimum amount required to accomplish the intended effect.
(b) The coating may be formulated from the following components, each used in the minimum quantity required to accomplish the intended effect:

- Substances generally recognized as safe for the purpose or previously sanctioned for the purpose.
- One or more of the following:
  - Component Limitations
  - Fatty acids ............................................................ Complying with § 172.860.
  - Oleic acid derived from tall oil fatty acids .............. Complying with § 172.862.
  - Partially hydrogenated rosin ................................ Catalytically hydrogenated to a maximum refractive index of 1.5012 at 100 °C. Color of WG or paler.
  - Pentaerythritol ester of maleic anhydride-modified wood rosin.
    - Acid number of 134–145; drop-softening point of 127 °C–173 °C; saponification number of less than 280; and a color of M or paler.
  - Do .......................................................... Acid number of 176–186; drop-softening point of 110 °C–118 °C; saponification number of less than 280; and a color of M or paler.
  - Polyethylene glycol .............................................. Complying with § 172.820. As a defoamer and dispersing adjuvant.
  - Polyhydric alcohol diesters of oxidatively refined (Gersthofen process) montan wax acids. Complying with § 178.3770 of this chapter and having a dropping point of 77 to 83 °C (170.6 to 181.4 °F), as determined by ASTM Method D566–76 (Reapproved 1982), “Standard Test Method for Dropping Point of Lubricating Grease,” which is incorporated by reference (Copies are available from the American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, 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) using as a solvent xylene-ethyl alcohol in a 2:1 ratio instead of toluene-ethyl alcohol in a 2:1 ratio.
  - Sodium lauryl sulfate ............................................ Complying with § 172.822. As a film former.
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Component Limitations
Wood rosin ........................................................... Color of K or paler.

(3) In lieu of the components listed in paragraph (b) (2) and (4) of this section, the following copolymer and one or more of the listed adjuvants.

Component Limitations
Vinyl chloride-vinylidene chloride copolymer As an aqueous dispersion containing a minimum of 75 percent water when applied.
Polyethylene glycol .............................................. Complying with § 172.820. As a defoamer and dispersing adjuvant.
Polyvinylpyrrolidone .............................................. As an adjuvant.
Potassium persulfate ............................................ Do.
Propylene glycol alginate ..................................... Do.
Sodium decylbenzenesulfonate ........................... Do.

(4) In lieu of the components listed in paragraph (b) (2) and (3) of this section, the following rosin derivative and either or both of the listed adjuvants:

Component Limitations
Calcium salt of partially dimerized rosin .............. Having a maximum drop-softening point of 197 °C and a color of H or paler. It is prepared by reaction with not more than 7 parts hydrated lime per 100 parts of partially dimerized rosin. The partially dimerized rosin is rosin that has been dimerized by sulfuric acid catalyst to a drop-softening point of 95 °C to 105 °C and a color of WG or paler.
Petroleum naphtha ............................................... As adjuvant. Complying with § 172.250.
Sperm oil .............................................................. As adjuvant.

§ 172.215 Coumarone-indene resin.

The food additive coumarone-indene resin may be safely used on grapefruit, lemons, limes, oranges, tangelos, and tangerines in accordance with the following prescribed conditions:

(a) The food additive is manufactured by the polymerization of a crude, heavy coal-tar solvent naphtha meeting the following specifications:
   (1) It is a mixture of indene, indan (hydrindene), substituted benzenes, and related compounds.
   (2) It contains no more than 0.25 percent tar bases.
   (3) 95 percent distills in the range 167 °C–184 °C.

(b) The food additive meets the following specifications:
   (1) Softening point, ring and ball: 126 °C minimum as determined by ASTM method E28–67 (Reapproved 1982), “Standard Test Method for Softening Point by Ring-and-Ball Apparatus,” which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, 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.
   (2) Refractive index (nD) 1.63–1.64.
   (c) It is used or intended for use as a protective coating for grapefruit, lemons, limes, oranges, tangelos, and tangerines whereby the maximum amount of the resin remaining on the fruit does not exceed 200 parts per million on a fresh-weight basis.

(d) To assure safe use of the additive:
   (1) The label of the market package or any intermediate premix of the additive shall bear, in addition to the other information required by the act:
      (i) The name of the additive, coumarone-indene resin.
      (ii) A statement of the concentration of the additive therein.

§ 172.225 Methyl and ethyl esters of fatty acids produced from edible fats and oils.

Methyl esters and ethyl esters of fatty acids produced from edible fats and oils may be safely used in food, subject to the following prescribed conditions:

(a) The additive consists of a mixture of either methyl or ethyl esters of fatty acids produced from edible fats and oils and meets the following specifications:

(1) Not less than 90 percent methyl or ethyl esters of fatty acids.

(2) Not more than 1.5 percent unsaponifiable matter.

(b) The additive is used or intended for use at the level not to exceed 3 percent by weight in an aqueous emulsion in dehydrating grapes to produce raisins, whereby the residue of the additive on the raisins does not exceed 200 parts per million.

§ 172.230 Microcapsules for flavoring substances.

Microcapsules may be safely used for encapsulating discrete particles of flavoring substances that are generally recognized as safe for their intended use or are regulated under this part, in accordance with the following conditions:

(a) The microcapsules may be formulated from the following components, each used in the minimum quantity required to accomplish the intended effect:

(1) Substances generally recognized as safe for the purpose.

(2) One or more of the following components:

<table>
<thead>
<tr>
<th>COMPONENT AND LIMITATIONS</th>
<th>LIMITATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Succinylated gelatin</td>
<td>Not to exceed 15 percent by combined weight of the microcapsule and flavoring oil. Succinic acid content of the gelatin is 4.5 to 5.5 percent.</td>
</tr>
</tbody>
</table>
(a) It is used as the salt(s) of one or more of the fatty acids meeting the requirements of §172.860, as a component of protective coatings applied to fresh fruits and vegetables.

(b) It is used at a level not in excess of that reasonably required to produce its intended effect.

§ 172.250 Petroleum naphtha.

Petroleum naphtha may be safely used in food in accordance with the following conditions:

(a) The additive is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature obtained from petroleum.

(b) The additive is refined to meet the following specifications when subjected to the procedures described in this paragraph.

(1) Boiling-point range: 175 °F–300 °F.

(2) Nonvolatile residue: 0.002 gram per 100 milliliters maximum.

(3) Ultraviolet absorbance limits, as follows:

<table>
<thead>
<tr>
<th>Wavelength (mill-microns)</th>
<th>Maximum absorbance per centimeter optical pathlength</th>
</tr>
</thead>
<tbody>
<tr>
<td>280–289</td>
<td>0.02</td>
</tr>
<tr>
<td>290–299</td>
<td>0.01</td>
</tr>
<tr>
<td>300–359</td>
<td>0.09</td>
</tr>
<tr>
<td>360–400</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Analytical Specification for Petroleum Naphtha

General Instructions

All glassware should be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure, it is recommended practice to rinse all glassware with purified isoctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of petroleum naphtha samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons found in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.
contents of the flask are evaporated on a steam bath until 1 milliliter of residue remains. Dissolve the 1 milliliters of hexadecane residue in isooctane and make up to 25 milliliters. Determine the absorbance in a 5-centimeter path length cell compared to isooctane as reference. The absorbance should not exceed 0.01 per centimeter path length. If necessary, isooctane may be purified by passage through a column of activated silica gel (Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent) or by distillation.

Methyl alcohol, A.C.S. reagent grade. Use 10 milliliters and proceed as with isooctane. The absorbance per centimeter of path length should be 0.00 between 280–400 μm. Methyl alcohol may be purified by simple distillation or by refluxing in the presence of potassium hydroxide (10 grams/2 liters) and zinc dust (25 grams/2 liters) for 3 hours followed by distillation.

n-Hexadecane, 99 percent olefin-free. Dilute 1.0 milliliter of n-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference between 280–400 μm. The absorbance per centimeter of path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

Sodium borohydride, 98 percent.

Water. All distilled water must be extracted with isooctane before use. A series of three successive extracts of 1.5 liters of distilled water with 100-milliliter portions of isooctane is satisfactory.

**PROCEDURE**

**Determination of ultraviolet absorbance.** Add a 25-milliliter aliquot of hydrocarbon solvent together with 1 milliliter of hexadecane to the 125-milliliter Erlenmeyer flask. While flushing with nitrogen, evaporate to 1 milliliter on a steam bath. Nitrogen is admitted through a 81-millimeter outer-diameter tube, drawn out into a 251-centimeter long and 15.5-millimeter inner-diameter capillary tip. This is positioned so that the capillary tip extends 4 centimeters into the flask. The nitrogen flow rate is such that the surface of the liquid is barely disturbed. After the volume is reduced to that of the 1 milliliter of hexadecane, the flask is left on the steam bath for 10 more minutes before removing. Add 10 milliliters of purified isooctane to the flask and reevaporate the solution to a 1-milliliter volume in the same manner as described above, except do not heat for an added 10 minutes. Repeat this operation twice more. Let the flask cool.

Add 10 milliliters of methyl alcohol and about 0.5 gram of sodium borohydride. (Minimize exposure of the borohydride to the atmosphere; a measuring dipper may be used.) Immediately fit a water-cooled condenser equipped with a 24/40 joint and with a drying tube into the flask, mix until the sodium borohydride is dissolved, and allow to stand for 30 minutes at room temperature, with intermittent swirling. At the end of this time, disconnect the flask and evaporate the methyl alcohol on the steam bath under nitrogen until sodium borohydride begins to drop out of solution. Remove the flask and let it cool.

Add 6 milliliters of isooctane to the flask and swirl to wash the crystalline slurry. Carefully transfer the isooctane extract to a 250-milliliter separatory funnel. Dissolve the crystals in the flask with about 25 milliliters of distilled water and pour this also into the separatory funnel. Adjust the water volume in the separatory funnel to about 100 milliliters and shake for 1 minute. After separation of the layers, draw off the aqueous layer into a second 250-milliliter separatory funnel. Transfer the hydrocarbon layer in the first funnel to a 25-milliliter volumetric flask.

Carefully wash the Erlenmeyer flask with an additional 6 milliliters of isooctane, swirl, and transfer to the second separatory funnel. Shake the funnel for 1 minute. After separation of the layers, draw off the aqueous layer into the first separatory funnel. Transfer the isooctane in the second funnel to the volumetric flask. Again wash the Erlenmeyer flask with an additional 6 milliliters of isooctane, swirl, and transfer to the first separatory funnel. Shake the funnel for 1 minute. After separation of the layers, draw off the aqueous layer and discard. Transfer the isooctane layer to the volumetric flask and adjust the volume to 25 milliliters of isooctane. Mix the contents well, then transfer to the first separatory funnel and wash twice with 50-milliliter portions of distilled water. Discard the aqueous layers after each wash.

Determine the ultraviolet absorbance of the isooctane extract in 5-centimeter path length cells compared to isooctane as reference between 280–400 μm. Determine a reagent blank concurrently with the sample, using 25 milliliters of purified isooctane instead of a solvent sample and measuring the ultraviolet absorbance of the blank between 280–400 μm.

The reagent blank absorbance should not exceed 0.04 per centimeter path length between 280–289 μm; 0.020 between 290–359 μm; and 0.010 between 360–400 μm.

**Determination of boiling-point range.** Use ASTM method D98–82, “Standard Method for Distillation of Petroleum Products,” which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, 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/

(c) Petroleum naphtha containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. Petroleum naphtha may contain antioxidants authorized for use in food in an amount not to exceed that reasonably required to accomplish the intended effect or to exceed any prescribed limitations.

(d) Petroleum naphtha is used or intended for use as a solvent in protective coatings on fresh citrus fruit in compliance with §172.210.

§ 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.

§ 172.260 Oxidized polyethylene.

Oxidized polyethylene may be safely used as a component of food, subject to the following restrictions:

(a) Oxidized polyethylene is the basic resin produced by the mild air oxidation of polyethylene. The polyethylene used in the oxidation process conforms to the density, maximum n-hexane extractable fraction, and maximum xylenel soluble fraction specifications prescribed in item 2.3 of the table in §177.1520(c) of this chapter. The oxidized polyethylene has a minimum number average molecular weight of 1,200, as determined by high temperature vapor pressure osmometry; contains a maximum of 5 percent by weight of total oxygen; and has an acid value of 9 to 19.

(b) The additive is used or intended for use as a protective coating or component of protective coatings for fresh avocados, bananas, beets, coconuts, eggplant, garlic, grapefruit, lemons, limes, mango, muskmelons, onions, oranges, papaya, peas (in pods), pineapple, plantain, pumpkin, rutabaga, squash (acorn), sweetpotatoes, tangerines, turnips, watermelon, Brazil nuts, chestnuts, filberts, hazelnuts, pecans, and walnuts (all nuts in shells).

(c) The additive is used in accordance with good manufacturing practice and in an amount not to exceed that required to produce the intended effect.

§ 172.270 Sulfated butyl oleate.

Sulfate butyl oleate may be safely used in food, subject to the following prescribed conditions:

(a) The additive is prepared by sulfation, using concentrated sulfuric acid, of a mixture of butyl esters produced by transesterification of an edible vegetable oil using 1-butanol. Following sulfation, the reaction mixture is washed with water and neutralized with aqueous sodium or potassium hydroxide. Prior to sulfation, the butyl oleate reaction mixture meets the following specifications:

(1) Not less than 90 percent butyl oleate.

(2) Not more than 1.5 percent unsaponifiable matter.

(b) The additive is used or intended for use at a level not to exceed 2 percent by weight in an aqueous emulsion in dehydrating grapes to produce raisins, whereby the residue of the additive on the raisins does not exceed 100 parts per million.

[57 FR 12711, Apr. 13, 1992]

§ 172.275 Synthetic paraffin and succinic derivatives.

Synthetic paraffin and succinic derivatives identified in this section may
be safely used as a component of food, subject to the following restrictions:

(a) The additive is prepared with 50 percent Fischer-Tropsch process synthetic paraffin, meeting the definition and specifications of §172.615, and 50 percent of such synthetic paraffin to which is bonded succinic anhydride and succinic acid derivatives of isopropyl alcohol, polyethylene glycol, and polypropylene glycol. It consists of a mixture of the Fischer-Tropsch process paraffin (alkane), alkyl succinic anhydride, alkyl succinic anhydride isopropyl half ester, dialkyl succinic anhydride polyethylene glycol half ester, and dialkyl succinic anhydride polypropylene glycol half ester, where the alkane (alkyl) has a chain length of 30–70 carbon atoms and the polyethylene and polypropylene glycols have molecular weights of 600 and 260, respectively.

(b) The additive meets the following specifications: Molecular weight, 880–930; melting point, 215–217 °F; acid number, 43–47; and saponification number, 75–78.

(c) It is used or intended for use as a protective coating or component of protective coatings for fresh grapefruit, lemons, limes, muskmelons, oranges, sweetpotatoes, and tangerines.

(d) It is used in an amount not to exceed that required to produce the intended effect.

§ 172.280 Terpene resin.

The food additive terpene resin may be safely used in accordance with the following prescribed conditions:

(a) The food additive is the beta-pinene polymer obtained by polymerizing terpene hydrocarbons derived from wood. It has a softening point of 112 °C–118 °C, as determined by ASTM method E28–67 (Reapproved 1982), “Standard Test Method for Softening Point By Ring-and-Ball Apparatus,” which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, 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.

(b) It is used or intended for use as follows:

(1) As a moisture barrier on soft gelatin capsules in an amount not to exceed 0.07 percent of the weight of the capsule.

(2) As a moisture barrier on powders of ascorbic acid or its salts in an amount not to exceed 7 percent of the weight of the powder.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10104, Mar. 19, 1984]

Subpart D—Special Dietary and Nutritional Additives

§ 172.310 Aluminum nicotinate.

Aluminum nicotinate may be safely used as a source of niacin in foods for special dietary use. A statement of the concentration of the additive, expressed as niacin, shall appear on the label of the food additive container or on that of any intermediate premix prepared therefrom.

§ 172.315 Nicotinamide-ascorbic acid complex.

Nicotinamide-ascorbic acid complex may be safely used in accordance with the following prescribed conditions:

(a) The additive is the product of the controlled reaction between ascorbic acid and nicotinamide, melting in the range 141 °C to 145 °C.

(b) It is used as a source of ascorbic acid and nicotinamide in multivitamin preparations.

§ 172.320 Amino acids.

The food additive amino acids may be safely used as nutrients added to foods in accordance with the following conditions:

(a) The food additive consists of one or more of the following individual amino acids in the free, hydrated or anhydrous form or as the hydrochloride, sodium or potassium salts:

L-Alanine
L-Arginine
L-Asparagine
L-Aspartic acid
L-Cysteine
L-Cystine
L-Glutamic acid
L-Glutamine
Aminoacetic acid (glycine)
L-Histidine
L-Isoleucine
Leucine
L-Lysine
DL-Methionine (not for infant foods)
L-Methionine
L-Phenylalanine
L-Proline
L-Threonine
L-Tryptophan
L-Tyrosine
L-Valine

(b) The food additive meets the following specifications:

(1) As found in “Food Chemicals Codex,” National Academy of Sciences/National Research Council (NAS/NRC), 3d Ed. (1981), which is incorporated by reference (Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, 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.) for the following:

L-Alanine
L-Arginine
L-Arginine Monohydrochloride
L-Cysteine Monohydrochloride
L-Cystine
Aminoacetic acid (glycine)
L-Leucine
DL-Methionine
L-Methionine
L-Tryptophan
L-Phenylalanine
L-Proline
L-Threonine
Glutamic Acid Hydrochloride
L-Isoleucine
L-Lysine Monohydrochloride
Monopotassium L-glutamate
L-Tyrosine
L-Valine

(2) As found in “Specifications and Criteria for Biochemical Compounds,” NAS/NRC Publication, 3rd Ed. (1972), 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, 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.) for the following:

L-Asparagine
L-Aspartic acid
L-Glutamine
L-Histidine

(c) The additive(s) is used or intended for use to significantly improve the biological quality of the total protein in a food containing naturally occurring primarily-intact protein that is considered a significant dietary protein source, provided that:

(1) A reasonable daily adult intake of the finished food furnishes at least 6.5 grams of naturally occurring primarily intact protein (based upon 10 percent of the daily allowance for the “reference” adult male recommended by the National Academy of Sciences in “Recommended Dietary Allowances,” NAS Publication No. 1694, 7th Ed. (1968), 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, 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.

(2) The additive(s) results in a protein efficiency ratio (PER) of protein in the finished ready-to-eat food equivalent to casein as determined by the method specified in paragraph (d) of this section.

(3) Each amino acid (or combination of the minimum number necessary to achieve a statistically significant increase) added results in a statistically significant increase in the PER as determined by the method described in paragraph (d) of this section. The minimum amount of the amino acid(s) to achieve the desired effect must be used and the increase in PER over the primarily-intact naturally occurring protein in the food must be substantiated.
§ 172.325 Bakers yeast protein.

Bakers yeast protein may be safely used in food in accordance with the following conditions:

(a) Bakers yeast protein is the insoluble proteinaceous material remaining after the mechanical rupture of yeast cells of Saccharomyces cerevisiae and removal of whole cell walls by centrifugation and separation of soluble cellular materials.

(b) The additive meets the following specifications on a dry weight basis:

(1) Zinc salts less than 500 parts per million (ppm) as zinc.

(d) Compliance with the limitations concerning PER under paragraph (c) of this section shall be determined by the method described in sections 43.212–43.216, “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., P.O. Box 901, 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. Each manufacturer or person employing the additive(s) under the provisions of this section shall keep and maintain throughout the period of his use of the additive(s) and for a minimum of 3 years thereafter, records of the tests required by this paragraph and other records required to assure effectiveness and compliance with this regulation and shall make such records available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration, or any other officer or employee acting on behalf of the Secretary of Health and Human Services and shall permit such officer or employee to conduct such inventories of raw and finished materials on hand as he deems necessary and otherwise to check the correctness of such records.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the Act, the following:

(1) The name of the amino acid(s) contained therein including the specific optical and chemical form.

(2) The amounts of each amino acid contained in any mixture.

(3) Adequate directions for use to provide a finished food meeting the limitations prescribed by paragraph (c) of this section.

(f) The food additive amino acids added as nutrients to special dietary foods that are intended for use solely under medical supervision to meet nutritional requirements in specific medical conditions and comply with the requirements of part 105 of this chapter are exempt from the limitations in paragraphs (c) and (d) of this section and may be used in such foods at levels not to exceed good manufacturing practices.
(3) Less than 0.3 ppm arsenic, 0.1 ppm cadmium, 0.4 ppm lead, 0.05 ppm mercury, and 0.3 ppm selenium.

(c) The viable microbial content of the finished ingredient is:

(1) Less than 10,000 organisms/gram by aerobic plate count.

(2) Less than 10 yeasts and molds/gram.

(3) Negative for Salmonella, E. coli, coagulase positive Staphylococci, Clostridium perfringens, Clostridium botulinum, or any other recognized microbial pathogen or any harmful microbial toxin.

(d) The ingredient is used in food as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

§ 172.340 Fish protein isolate.

(a) The food additive fish protein isolate may be safely used as a food supplement in accordance with the following prescribed conditions:

(1) The additive shall consist principally of dried fish protein prepared from the edible portions of fish after removal of the heads, fins, tails, bones, scales, viscera, and intestinal contents.

(2) The additive shall be derived only from species of bony fish that are generally recognized by qualified scientists as safe for human consumption and that can be processed as prescribed to meet the required specifications.

(3) Only wholesome fresh fish otherwise suitable for human consumption may be used. The fish shall be handled expeditiously under sanitary conditions. These conditions shall be in accordance with recognized good manufacturing practice for fish to be used as human food.

(4) The additive shall be prepared by extraction with hexane and food-grade ethanol to remove fat and moisture. Solvent residues shall be reduced by drying.

(b) The food additive meets the following specifications: (Where methods of determination are specified, they are Association of Official Analytical Chemists Methods, 13th ed., 1980, which are incorporated by reference).

(1) Protein content, as N × 6.25, shall not be less than 90 percent by weight of the final product, as determined by the method described in section 2.057, Improved Kjeldahl Method for Nitrate-Free Samples (20)—Official Final Action.

(2) Moisture content shall not be more than 10 percent by weight of the final product, as determined by the method described in section 24.003, Air Drying (1)—Official First Action.

(3) Fat content shall not be more than 0.5 percent by weight of the final product, as determined by the method described in section 24.005, Crude Fat or Ether Extract—Official Final Action.

(4) Solvent residues in the final product shall not be more than 5 parts per

§ 172.340 Fish protein isolate.

(a) The food additive fish protein isolate may be safely used as a food supplement in accordance with the following prescribed conditions:

(1) The additive shall consist principally of dried fish protein prepared from the edible portions of fish after removal of the heads, fins, tails, bones, scales, viscera, and intestinal contents.

(2) The additive shall be derived only from species of bony fish that are generally recognized by qualified scientists as safe for human consumption and that can be processed as prescribed to meet the required specifications.

(3) Only wholesome fresh fish otherwise suitable for human consumption may be used. The fish shall be handled expeditiously under sanitary conditions. These conditions shall be in accordance with recognized good manufacturing practice for fish to be used as human food.

(4) The additive shall be prepared by extraction with hexane and food-grade ethanol to remove fat and moisture. Solvent residues shall be reduced by drying.

(b) The food additive meets the following specifications: (Where methods of determination are specified, they are Association of Official Analytical Chemists Methods, 13th ed., 1980, which are incorporated by reference).

(1) Protein content, as N × 6.25, shall not be less than 90 percent by weight of the final product, as determined by the method described in section 2.057, Improved Kjeldahl Method for Nitrate-Free Samples (20)—Official Final Action.

(2) Moisture content shall not be more than 10 percent by weight of the final product, as determined by the method described in section 24.003, Air Drying (1)—Official First Action.

(3) Fat content shall not be more than 0.5 percent by weight of the final product, as determined by the method described in section 24.005, Crude Fat or Ether Extract—Official Final Action.

(4) Solvent residues in the final product shall not be more than 5 parts per

1Copies are available from: AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or 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.
§ 172.345 Folic acid (folacin).

Folic acid (CAS Reg. No. 59–30–3), also known as folacin or folate, may be safely used in food as a nutrient in accordance with the following prescribed conditions:

(a) Folic acid is the chemical \(\text{N}^\text{4-[(2-amino-1,4-dihydro-4-oxo-6-pteridinyl)methyl]amino}benzoyl}\) L-glutamic acid.

(b) Folic acid meets the specifications of the “Food Chemicals Codex,” 4th ed. (1996), pp. 157–158, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address http://www.nap.edu), or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 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.

(c) Folic acid may be added to foods subject to a standard of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act (the act) when the standard of identity specifically provides for the addition of folic acid.

(d) Folic acid may be added, at levels not to exceed 400 micrograms (\(\mu\)g) per serving, to breakfast cereals, as defined under §170.3(n)(4) of this chapter, and to corn grits at a level such that each pound of corn grits contains not more than 1.0 milligram of folic acid.

(e) Folic acid may be added to infant formula in accordance with section 412(1)(1) of the act or with regulations issued under section 412(1)(2) of the act which are codified in §107.100 of this chapter.

(f) Folic acid may be added to a medical food, as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), at levels not to exceed the amount necessary to meet the distinctive nutritional requirements of the disease or condition for which the food is formulated.

(g) Folic acid may be added to food for special dietary use at levels not to exceed the amount necessary to meet the special dietary needs for which the food is formulated.

(h) Folic acid may be added to foods represented as meal-replacement products, in amounts not to exceed:

- (1) Four hundred \(\mu\)g per serving if the food is a meal-replacement that is represented for use once per day; or
- (2) Two hundred \(\mu\)g per serving if the food is a meal-replacement that is represented for use more than once per day.


§ 172.350 Fumaric acid and salts of fumaric acid.

Fumaric acid and its calcium, ferrous, magnesium, potassium, and sodium salts may be safely used in food in accordance with the following prescribed conditions:

(a) The additives meet the following specifications:

- (1) Fumaric acid contains a minimum of 99.5 percent by weight of fumaric acid, calculated on the anhydrous basis.
- (2) The calcium, magnesium, potassium, and sodium salts contain a minimum of 99 percent by weight of the respective salt, calculated on the anhydrous basis. Ferrous fumarate contains a minimum of 31.3 percent total iron and not more than 2 percent ferric iron.

(b) With the exception of ferrous fumarate, fumaric acid and the named salts are used singly or in combination in food at a level not in excess of the amount reasonably required to accomplish the intended effect.

(c) Ferrous fumarate is used as a source of iron in foods for special dietary use, when the use is consistent with good nutrition practice.
§ 172.365 Kelp.
Kelp may be safely added to a food as a source of the essential mineral iodine, provided the maximum intake of the food as may be consumed during a period of one day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive so as to provide a total amount of iodine in excess of 225 micrograms for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 45 micrograms for infants, 105 micrograms for children under 4 years of age, 225 micrograms for adults and children 4 or more years of age, and 300 micrograms for pregnant or lactating women. The food additive kelp is the dehydrated, ground product prepared from Macrocystis pyrifera, Laminaria digitata, Laminaria saccharina, and Laminaria cloustoni.

§ 172.370 Iron-choline citrate complex.
Iron-choline citrate complex made by reacting approximately equimolecular quantities of ferric hydroxide, choline, and citric acid may be safely used as a source of iron in foods for special dietary use.

§ 172.372 N-Acetyl-L-methionine.
The food additive N-acetyl-L-methionine may be safely added to food (except infant foods and foods containing added nitrites/nitrates) as a source of L-methionine for use as a nutrient in accordance with the following conditions:

(a) N-Acetyl-L-methionine (Chemical Abstracts Service Registry No. 65–82–7) is the derivative of the amino acid methionine formed by addition of an acetyl group to the alpha-amino group of methionine. It may be in the free, hydrated or anhydrous form, or as the sodium or potassium salts.

(b) The additive meets the following specifications:

(1) Purity assay, on a dry basis: Minimum 99 percent.
(2) Residue on ignition: Maximum 0.1 percent.
(3) Specific optical rotation \([\alpha]_D^25\), Between −19° and −23°.
(4) The additive may contain residues of not more than 50 ppm ethyl alcohol; 10 ppm methyl alcohol; and 10 ppm acetone, when used as processing solvents.

(c) The additive is used or intended for use as a source of L-methionine to improve significantly the biological quality of the total protein in a food containing naturally occurring primarily intact vegetable protein that is considered a significant dietary protein source, provided that:

(1) A reasonable daily adult intake of the finished food furnishes at least 6.5 grams of naturally occurring primarily intact vegetable protein.

(2) The additive results in a protein efficiency ratio (PER) of protein in the finished ready-to-eat food equivalent to casein as determined by the method specified in paragraph (d) of this section.

(3) The use of the additive results in a statistically significant increase in the PER as determined by the method described in paragraph (d) of this section. The minimum amount of the additive to achieve the desired effect must be used, and the increase in PER over the primarily intact naturally occurring vegetable protein in the food must be substantiated as a statistically significant difference with at least a probability (P) value of less than 0.05.

(4) The amount of the additive added for nutritive purpose shall not exceed the level that will provide a total of 3.1 percent L- and DL-methionine (expressed as the free amino acid) by weight of the total protein of the finished food, including the amount naturally present in free and combined (as protein) form.

(5) The additive shall not be added to infant foods or to foods containing added nitrites/nitrates.

(d) Compliance with the limitations concerning PER under paragraph (c) of the section shall be determined by the method described in sections 43.212–43.216, “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.
§ 172.375 Potassium iodide.

The food additive potassium iodide may be safely used in accordance with the following prescribed conditions:

(a) Potassium iodide may be safely added to a food as a source of the essential mineral iodine, provided the maximum intake of the food as may be consumed during a period of one day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive so as to provide a total amount of iodine in excess of 225 micrograms for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 45 micrograms for infants, 105 micrograms for children under 4 years of age, 225 micrograms for children 4 or more years of age, and 300 micrograms for pregnant or lactating women.

(b) To assure safe use of the additive, in addition to the other information required by the Act, the label of the additive shall bear:

(1) The name of the additive.

(2) A statement of the concentration of the additive in any mixture.

§ 172.379 Vitamin D₂.

Vitamin D₂ may be used safely in foods as a nutrient supplement defined under §170.3(o)(20) of this chapter in accordance with the following prescribed conditions:

(a) Vitamin D₂, also known as ergocalciferol, is the chemical 9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol. Vitamin D₂ is produced by ultraviolet irradiation of ergosterol isolated from yeast and is purified by crystallization.

(b) Vitamin D₂ meets the specifications of the Food Chemicals Codex, 6th ed. (2008), pp. 1013 and 1014, which is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C 552(a) and 1 CFR part 51. You may obtain a copy from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address: http://www.usp.org). You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1071, or at the National Archives and Records Administration.
Food and Drug Administration, HHS § 172.380

Vitamin D₃ may be used safely in foods as a nutrient supplement defined under §170.3(o)(20) of this chapter in accordance with the following prescribed conditions:

(a) Vitamin D₃, also known as cholecalciferol, is the chemical 9,10-seco(5Z,7E)-5,7,10(19)-cholestatrien-3-ol. Vitamin D₃ occurs in and is isolated from fish liver oils. It also is manufactured by ultraviolet irradiation of 7-dehydrocholesterol produced from cholesterol and is purified by crystallization.

(b) Vitamin D₃ meets the specifications of the Food Chemicals Codex, 5th ed. (2004), pp. 498–499, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the National Academy Press, 500 Fifth St. NW., Washington, DC 20001 (Internet address http://www.nap.edu). Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 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.

(c) The additive may be used as follows:

<table>
<thead>
<tr>
<th>Category of Food</th>
<th>Maximum Levels in Food (as Served)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soy beverages</td>
<td>50 International Units (IU)/100 grams (g)</td>
</tr>
<tr>
<td>Soy beverage products</td>
<td>89 IU/100 g</td>
</tr>
<tr>
<td>Soy-based butter substitute spreads</td>
<td>330 IU/100 g</td>
</tr>
<tr>
<td>Soy-based cheese substitutes and soy-based cheese substitute products</td>
<td>270 IU/100 g</td>
</tr>
</tbody>
</table>

(c) The additive may be used as follows:

(1) At levels not to exceed 100 International Units (IU) per 240 milliliters (mL) in 100 percent fruit juices (as defined under §170.3(n)(35) of this chapter) that are fortified with greater than or equal to 33 percent of the reference daily intake (RDI) of calcium per 240 mL, excluding fruit juices that are specially formulated or processed for infants.

(2) At levels not to exceed 100 IU per 240 mL in fruit juice drinks (as defined under §170.3(n)(35) of this chapter) that are fortified with greater than or equal to 10 percent of the RDI of calcium per 240 mL, excluding fruit juice drinks that are specially formulated or processed for infants.

(3) At levels not to exceed 140 IU per 240 mL (prepared beverage) in soy-protein based meal replacement beverages (powder or liquid) that are represented for special dietary use in reducing or maintaining body weight in accordance with §105.66 of this chapter.

(4) At levels not to exceed 100 IU per 40 grams in meal replacement bars or other-type bars that are represented for special dietary use in reducing or maintaining body weight in accordance with §105.66 of this chapter.

(5) At levels not to exceed 81 IU per 30 grams in cheese and cheese products as defined under §170.3(n)(5) of this chapter, excluding cottage cheese, ricotta cheese, and hard grating cheeses such as Parmesan and Romano as defined in §§133.165 and 133.183 of this chapter, and those defined by standard of identity in §133.148 of this chapter.

[74 FR 11022, Mar. 16, 2009]
§ 172.385 Whole fish protein concentrate.

The food additive whole fish protein concentrate may be safely used as a food supplement in accordance with the following prescribed conditions:

(a) The additive is derived from whole, wholesome hake and hakelike fish, herring of the genera Clupea, menhaden, and anchovy of the species Engraulis mordax, handled expeditiously and under sanitary conditions in accordance with good manufacturing practices recognized as proper for fish that are used in other forms for human food.

(b) The additive consists essentially of a dried fish protein processed from the whole fish without removal of heads, fins, tails, viscera, or intestinal contents. It is prepared by solvent extraction of fat and moisture with isopropyl alcohol or with ethylene dichloride followed by isopropyl alcohol, except that the additive derived from herring, menhaden and anchovy is prepared by solvent extraction with isopropyl alcohol alone. Solvent residues are reduced by conventional heat drying and/or microwave radiation and there is a partial removal of bone.

(c) The food additive meets the following specifications:

(1) Protein content (N × 6.25) shall not be less than 75 percent by weight of the final product, as determined by the method described in section 2.057 in “Official Methods of Analysis of the Association of Official Analytical Chemists” (AOAC), 13th Ed. (1980). Protein quality shall not be less than 100, as determined by the method described in sections 43.212–43.216 of the AOAC. The 13th Ed. is incorporated by reference, and 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.

(2) Moisture content shall not exceed 10 percent by weight of the final product, as determined by the method described in section 24.003 of the AOAC. See paragraph (c)(1) of this section for availability of the material incorporated by reference.

(3) Fat content shall not exceed 0.5 percent by weight of the final product, as determined by the method described in section 24.005 of the AOAC. See paragraph (c)(1) of the this section for availability of the material incorporated by reference.

(4) The additive may contain residues of isopropyl alcohol and ethylene dichloride not in excess of 250 parts per million and 5 parts per million, respectively, when used as solvents in the extraction process.

(5) Microwave radiation meeting the requirements of §179.30 of this chapter may be used to reduce residues of the solvents used in the extraction process.

(6) The additive shall contain not in excess of 100 parts per million fluoride (expressed as F).

(7) The additive shall be free of Escherichia coli and pathogenic organisms, including Salmonella, and shall have a total bacterial plate count of not more than 10,000 per gram.

(8) The additive shall have no more than a faint characteristic fish odor and taste.

(d) When the additive is used or intended for use in the household as a protein supplement in food for regular consumption by children up to 8 years of age, the amount of the additive from this source shall not exceed 20 grams per day (about one heaping tablespoon).

(e) When the additive is used as a protein supplement in manufactured food, the total fluoride content (expressed as F) of the finished food shall not exceed 8 ppm based on the dry weight of the food product.

(f) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of consumer-sized or bulk containers of the additive shall bear the name “whole fish protein concentrate”.

(2) The label or labeling of containers of the additive shall bear adequate directions for use to comply with the limitations prescribed by paragraphs (d) and (e) of this section.
(3) Labels of manufactured foods containing the additive shall bear, in the ingredient statement, the name of the additive, “whole fish protein concentrate” in the proper order of decreasing predominance in the finished food.

§ 172.395 Xylitol.

Xylitol may be safely used in foods for special dietary uses, provided the amount used is not greater than that required to produce its intended effect.

§ 172.399 Zinc methionine sulfate.

Zinc methionine sulfate, CAS Reg. No. 56329–42–1, may be safely used in accordance with the following prescribed conditions:

(a) It is used as the product of the reaction between equimolar amounts of zinc sulfate and DL-methionine in purified water.

(b) The additive meets the following specifications:

- Zinc content—19 to 22 percent.
- C₅H₁₁NO₂S “DL-methionine”—46 to 50 percent.
- Cadmium—not more than 0.05 part per million.

(c) The additive is used in tablet form as a source of dietary zinc.

§ 172.410 Calcium silicate.

Calcium silicate, including synthetic calcium silicate, may be safely used in food in accordance with the following prescribed conditions:

(a) It is used as an anticaking agent in food in an amount not in excess of that reasonably required to produce its intended effect.

(b) It will not exceed 2 percent by weight of the food, except that it may be present up to 5 percent by weight of baking powder.

§ 172.430 Iron ammonium citrate.

Iron ammonium citrate may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is the chemical green ferric ammonium citrate.

(b) The additive is used, or intended for use as an anticaking agent in salt for human consumption so that the level of iron ammonium citrate does not exceed 25 parts per million (0.0025 percent) in the finished salt.

(c) To assure safe use of the additive the label or labeling of the additive shall bear, in addition to the other information required by the Act:

1. The name of the additive.

2. Adequate directions to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

§ 172.480 Silicon dioxide.

The food additive silicon dioxide may be safely used in food in accordance with the following conditions:

(a) It is used as a stabilizer in the production of beer, and is removed from the beer by filtration prior to final processing.

(b) It is used or intended for use as an adsorbent for dl-a-tocopheryl acetate and pantothenyl alcohol in tableted foods for special dietary use, in an amount not greater than that required to accomplish the intended physical or technical effect.

§ 172.490 Yellow prussiate of soda.

(a) The food additive yellow prussiate of soda (sodium ferrocyanide decahydrate; Na₄Fe(CN)₆·10H₂O contains a minimum of 99 percent by weight of sodium ferrocyanide decahydrate.

(b) The additive is used or intended for use as an anticaking agent in salt as an adjuvant in the production of dendritic crystals of salt in an amount
Subpart F—Flavoring Agents and Related Substances

§172.510 Natural flavoring substances and natural substances used in conjunction with flavors.

Natural flavoring substances and natural adjuvants may be safely used in food in accordance with the following conditions:

<table>
<thead>
<tr>
<th>Common name</th>
<th>Scientific name</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aloe</td>
<td>Aloe pernyi Baker, A. barbadensis Mill., A. ferox Mill., and hybrids of this sp. with A. africana Mill. and A. spicata Baker.</td>
<td>In alcoholic beverages only</td>
</tr>
<tr>
<td>Althea root and flowers</td>
<td>Althea officinalis L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Amryis (West Indian sandalwood)</td>
<td>Amryis balsamifera L.</td>
<td>Finished food thujone free¹</td>
</tr>
<tr>
<td>Angora weed</td>
<td>Rocioella fuciformis Ach</td>
<td>In alcoholic beverages only</td>
</tr>
<tr>
<td>Arnica flowers</td>
<td>Arnica montana L., A. fulgens Pursh., A. sororia Greene, or A. cordifolia Hooker.</td>
<td>Do.</td>
</tr>
<tr>
<td>Artemisia (wormwood)</td>
<td>Artemisia spp</td>
<td>Do.</td>
</tr>
<tr>
<td>Artichoke leaves</td>
<td>Cynara scolymus L</td>
<td>In alcoholic beverages only</td>
</tr>
<tr>
<td>Benzoin resin</td>
<td>Styrox benzoin Dryander, S. paralleleeneurs Perkins, S. tonkinensis (Pierre) Craib ex Hartwich, or other spp. of the Section Anthostyrax of the genus Styrox.</td>
<td></td>
</tr>
<tr>
<td>Blackberry bark</td>
<td>Rubus, Section Eubatus</td>
<td>Do.</td>
</tr>
<tr>
<td>Boldus (boldo) leaves</td>
<td>Peumus boldus Mol</td>
<td>Do.</td>
</tr>
<tr>
<td>Boronia flowers</td>
<td>Boronia megastigmae Nees.</td>
<td>Do.</td>
</tr>
<tr>
<td>Bryonia root</td>
<td>Bryonia alba L., or B. dioica Jacc.</td>
<td>Do.</td>
</tr>
<tr>
<td>Buchu leaves</td>
<td>Barosma betulina Bartl. et Wendl., B. crenulata (L.) Hook. or B. serratifolia Wild.</td>
<td>Do.</td>
</tr>
<tr>
<td>Buckwheat leaves</td>
<td>Menyanthès Inratolata L</td>
<td>Do.</td>
</tr>
<tr>
<td>Calumba root</td>
<td>Melaleuca leucadendron L. and other Melaleuca spp.</td>
<td>Do.</td>
</tr>
<tr>
<td>Camphor tree</td>
<td>Cinnamomum camphora (L.) Nees et Eberm.</td>
<td>Do.</td>
</tr>
<tr>
<td>Cascara sagrada</td>
<td>Rhamnus purshiana DC</td>
<td>Do.</td>
</tr>
<tr>
<td>Cassie flowers</td>
<td>Acacia farnesiana (L.) Wild.</td>
<td>Do.</td>
</tr>
<tr>
<td>Castor oil</td>
<td>Ricinus communis L</td>
<td>Do.</td>
</tr>
<tr>
<td>Catechu, black</td>
<td>Acacia catechu Wild</td>
<td>Do.</td>
</tr>
<tr>
<td>Cedar, white (aborvitae), leaves and twigs</td>
<td>Thuya occidentalis L</td>
<td>Safrole free</td>
</tr>
<tr>
<td>Centuary</td>
<td>Centaurium umbellatum Gilib</td>
<td>Finished food thujone free¹</td>
</tr>
<tr>
<td>Cherry pits</td>
<td>Prunus avium L. or P. cerasus L</td>
<td>In alcoholic beverages only</td>
</tr>
<tr>
<td>Cherry-laurel leaves</td>
<td>Prunus laurocerasus L</td>
<td>Not to exceed 25 p.p.m. prussic acid</td>
</tr>
<tr>
<td>Chestnut leaves</td>
<td>Castanea dentata (Marsh.) Borkh.</td>
<td>Do.</td>
</tr>
<tr>
<td>Chirata</td>
<td>Swertia chirata Buch.-Harm</td>
<td>In alcoholic beverages only</td>
</tr>
<tr>
<td>Cinchona, red, bark</td>
<td>Cinchona succoobruna Pav. or its hybrids</td>
<td>In beverages only; not more than 83 p.p.m. total cinchona alkaloids in finished beverage Do.</td>
</tr>
<tr>
<td>Cinchona, yellow, bark</td>
<td>Cinchona ledgeriana Moens., C. calisaya Weid., or hybrids of these with other spp. of Cinchona.</td>
<td></td>
</tr>
<tr>
<td>Copaiba</td>
<td>Quercus suber L., or Q. occidentalis F. Gay</td>
<td>In alcoholic beverages only</td>
</tr>
<tr>
<td>Cork, oak</td>
<td>South American spp. of Copaifera L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Costmary</td>
<td>Chrysanthemum balsamita L</td>
<td>Do.</td>
</tr>
<tr>
<td>Common name</td>
<td>Scientific name</td>
<td>Limitations</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Costus root</td>
<td>Sausurea lappa Clarke.</td>
<td></td>
</tr>
<tr>
<td>Cubeb</td>
<td>Piper cubeba L. f.</td>
<td></td>
</tr>
<tr>
<td>Currant, black, buds and leaves</td>
<td>Ribes nigrum L. sarmient L.</td>
<td></td>
</tr>
<tr>
<td>Damiana leaves</td>
<td>Tumana diffusa Wall.</td>
<td></td>
</tr>
<tr>
<td>Davana</td>
<td>Artemisia pallens Wall.</td>
<td></td>
</tr>
<tr>
<td>Dittany (frasinelia) roots</td>
<td>Dictamnus abus L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Dittany of Crete</td>
<td>Origanum dictamnus L.</td>
<td></td>
</tr>
<tr>
<td>Dragon's blood (draconubin)</td>
<td>Daemonorops spp.</td>
<td></td>
</tr>
<tr>
<td>Elder tree leaves</td>
<td>Sambucus nigra L.</td>
<td>In alcoholic beverages only; not to exceed 25 p.p.m. prussic acid in the flavor</td>
</tr>
<tr>
<td>Elecampane rhizome and roots</td>
<td>Inula helemium L.</td>
<td>In alcoholic beverages only.</td>
</tr>
<tr>
<td>Elemi</td>
<td>Canarium commune L. or C. luteocinum Miq.</td>
<td></td>
</tr>
<tr>
<td>Erigeron</td>
<td>Erigeron canadensis L.</td>
<td></td>
</tr>
<tr>
<td>Eucalyptus globulus leaves</td>
<td>Eucalyptus globulus Labill.</td>
<td></td>
</tr>
<tr>
<td>Fir (&quot;pine&quot;) needles and twigs</td>
<td>Abies sibirica Ledeb., A. alba Mill., A. sachalinensis Masters or A. mayriana Miyabe et Kudo.</td>
<td></td>
</tr>
<tr>
<td>Fire, balsam, needles and twigs</td>
<td>Abies balsamea (L.) Mill.</td>
<td></td>
</tr>
<tr>
<td>Galanga, greater</td>
<td>Alpinia galanga Wild</td>
<td>Do.</td>
</tr>
<tr>
<td>Galbanum</td>
<td>Ferula galbaniflora Boiss. et Buhse and other Ferula spp.</td>
<td></td>
</tr>
<tr>
<td>Gambrir (catechu, pale)</td>
<td>Uncaria gambrir Roxb.</td>
<td></td>
</tr>
<tr>
<td>Genet flowers</td>
<td>Spartium junceum L.</td>
<td></td>
</tr>
<tr>
<td>Gentian, stemless</td>
<td>Gentiana acaulis L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Germander, chamaedrys</td>
<td>Teucrium chamaedrys L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Germander, golden</td>
<td>Teucrium polium L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Guaiazic</td>
<td>Guaiacum officinale L., G. santum L., Buinesia samrient L.</td>
<td></td>
</tr>
<tr>
<td>Guarana</td>
<td>Paulinia cupana HBK.</td>
<td></td>
</tr>
<tr>
<td>Haw, black, bark</td>
<td>Viburnum prunifolium L.</td>
<td></td>
</tr>
<tr>
<td>Hemlock needles and twigs</td>
<td>Tauge canadensis (L.) Carr. or T. heterophylla (Raf.) Sarg.</td>
<td></td>
</tr>
<tr>
<td>Hyacinth flowers</td>
<td>Hyacinthus orientalis L.</td>
<td></td>
</tr>
<tr>
<td>Iceland moss</td>
<td>Cetraria islandica Ach</td>
<td></td>
</tr>
<tr>
<td>Imperatoria</td>
<td>Peucedanum ostruthium (L.) Koch (Imperatoria ostruthium L.).</td>
<td>Do.</td>
</tr>
<tr>
<td>Iva</td>
<td>Achillea mosahtaca Jacq</td>
<td></td>
</tr>
<tr>
<td>Labdanum</td>
<td>Cistus spp.</td>
<td></td>
</tr>
<tr>
<td>Lemon-verbenum</td>
<td>Lippia citroidora HBK.</td>
<td>Do.</td>
</tr>
<tr>
<td>Linalone wood</td>
<td>Bursera delpechiana Poiss. and other Bursera spp.</td>
<td></td>
</tr>
<tr>
<td>Linden leaves</td>
<td>Tilia spp.</td>
<td>Do.</td>
</tr>
<tr>
<td>Lovage</td>
<td>Levisticum officinale Koch.</td>
<td></td>
</tr>
<tr>
<td>Lungmoss (lungwort)</td>
<td>Sticta pulmonacea Ach.</td>
<td>Do.</td>
</tr>
<tr>
<td>Maidenhair fern</td>
<td>Asiantanum capilus-veneis L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Maple, mountain</td>
<td>Acer spicatum Lam.</td>
<td></td>
</tr>
<tr>
<td>Mimosa (black wattle) flowers</td>
<td>Acacia decurrens Wild. var. dealbata</td>
<td></td>
</tr>
<tr>
<td>Mullein flowers</td>
<td>Verbascum phlomoides L. or V. thapsiforme Schrad Commiphora molmol Engl., C. abyssinica (Berg) Engl., or other Commiphora spp.</td>
<td>Do.</td>
</tr>
<tr>
<td>Myrrh</td>
<td>Myrthus communis L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Myrtle leaves</td>
<td>Myrtus communis L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Oak, English, wood</td>
<td>Quercus robur L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Oak, white, chips</td>
<td>Quercus alba L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Oak moss</td>
<td>Eremia prunastri (L.) Ach., E. furtuacea (L.) Mann, and other lichens.</td>
<td>Finished food thujone free (^1)</td>
</tr>
<tr>
<td>Olibanum</td>
<td>Boswellia carteri Birdw. and other Boswellia spp.</td>
<td></td>
</tr>
<tr>
<td>Opopanax (bisabolmyrth)</td>
<td>Opopanax chironium Koch (true opopanax) of Commiphora erythraea Eng. var. Llabrescens. iris germanica L. (including its variety florentina Dykes) and I. patula Lam.</td>
<td></td>
</tr>
<tr>
<td>Oris root</td>
<td>Iris germanica L. (including its variety florentina Dykes) and I. patula Lam.</td>
<td></td>
</tr>
<tr>
<td>Parsy</td>
<td>Vicia tricolor L.</td>
<td>In alcoholic beverages only.</td>
</tr>
<tr>
<td>Passion flower</td>
<td>Passiflora incarnata L.</td>
<td></td>
</tr>
<tr>
<td>Patchouly</td>
<td>Pogostemon cadin Berth. and P. heymenus Berth.</td>
<td>In alcoholic beverages only; not to exceed 25 p.p.m. prussic acid in the flavor</td>
</tr>
<tr>
<td>Peach leaves</td>
<td>Prunus persica (L.) Batsch</td>
<td></td>
</tr>
<tr>
<td>Pennyroyal, American</td>
<td>Hedecoma pulegioides (L.) Pers.</td>
<td></td>
</tr>
<tr>
<td>Pennyroyal, European</td>
<td>Mentha pulegium L.</td>
<td></td>
</tr>
<tr>
<td>Common name</td>
<td>Scientific name</td>
<td>Limitations</td>
</tr>
<tr>
<td>-------------</td>
<td>-----------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Yellow pine, dwarf, needles and twigs</td>
<td>Pinus mugo Turra var. pumilio (Haenke) Zénari.</td>
<td>In alcoholic beverages only</td>
</tr>
<tr>
<td>Pine, Scotch, needles and twigs</td>
<td>Pinus sylvestris L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Pine, white, bark</td>
<td>Pinus strobus L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Pine, white oil</td>
<td>Pinus palustris Mill., and other Pinus spp.</td>
<td>In alcoholic beverages only</td>
</tr>
<tr>
<td>Poplar buds</td>
<td>Populus balsamifera L. (P. tacamahacca Mill.), P. candidans Ait., or P. nigra L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Quassia</td>
<td>Picrasma excelsa (Sw.) Flanch., or Quassia amara L.</td>
<td>Schinopsis lorentzii (Griseb.) Engl.</td>
</tr>
<tr>
<td>Quebracho bark</td>
<td>Aspidosperma quebracho-blanco Schlecht., or (Quebrachia lorentzii) (Griseb.).</td>
<td>Do.</td>
</tr>
<tr>
<td>Quillaja (soapbark)</td>
<td>Quillaja saponaria Mol.</td>
<td>In alcoholic beverages only</td>
</tr>
<tr>
<td>Red saunders (red sandalwood)</td>
<td>Pterocarpus santalinus</td>
<td>Do.</td>
</tr>
<tr>
<td>Rhamnus root</td>
<td>Rhamnus cathartica L.</td>
<td>Hypericin-free alcohol distillate form only; in alcoholic beverages only</td>
</tr>
<tr>
<td>Rhus, garden root</td>
<td>Rhus glabra L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Rhus root</td>
<td>Rhus typhina L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Roselle</td>
<td>Hibiscus sabdariffa L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Rosin (colophony)</td>
<td>Pinus palustris Mill., and other Pinus spp</td>
<td>Do.</td>
</tr>
<tr>
<td>St. Johnswort leaves, flowers, and caulis</td>
<td>Hypericum perforatum L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Violet, Swiss</td>
<td>Viola odorata L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Sassafras leaves</td>
<td>Sassafras albidum (Nutt.) Nees</td>
<td>In alcoholic beverages only</td>
</tr>
<tr>
<td>Senna, Alexandria</td>
<td>Cassia acutifolia Delile.</td>
<td>Do.</td>
</tr>
<tr>
<td>Serpentaria (Virginia snakeroot)</td>
<td>Aristolochia serpentaria L.</td>
<td>In alcoholic beverages only</td>
</tr>
<tr>
<td>Simaruba bark</td>
<td>Simarubum amara Mill.</td>
<td>Do.</td>
</tr>
<tr>
<td>Snakeroot, Canadian (wild ginger)</td>
<td>Asarum canadense L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Spruce needles and twigs</td>
<td>Picea glauca (Moench) Voss or P. mariana (Mill.)</td>
<td>In alcoholic beverages only; finished alcoholic beverages thujone free</td>
</tr>
<tr>
<td>Storax (styrax)</td>
<td>Liquidambar orientalis Mill. or L. styraciflua L.</td>
<td>As oil only</td>
</tr>
<tr>
<td>Tagetes (marigold)</td>
<td>Tagetes patula L., T. erecta L., or T. minuta L. (T. glandulifera Schrank.)</td>
<td>Do.</td>
</tr>
<tr>
<td>Tansy</td>
<td>Tanacetum vulgare L.</td>
<td>In alcoholic beverages only; finished alcoholic beverages thujone free</td>
</tr>
<tr>
<td>Thistle, blessed (holy thistle)</td>
<td>Oniscus benedictus L.</td>
<td>In alcoholic beverages only</td>
</tr>
<tr>
<td>Thyme</td>
<td>Thymus capitus Hoffmg. et Link.</td>
<td>Do.</td>
</tr>
<tr>
<td>Tolu</td>
<td>Myroxylon balsamum (L.) Harms.</td>
<td>Do.</td>
</tr>
<tr>
<td>Turpentine</td>
<td>Pinus palustris Mill. and other Pinus spp. which yield terpene oils exclusively.</td>
<td>Do.</td>
</tr>
<tr>
<td>Valerian rhizome and roots</td>
<td>Valeriana officinalis L.</td>
<td>In alcoholic beverages only; finished alcoholic beverages thujone free</td>
</tr>
<tr>
<td>Veronica</td>
<td>Veronica officinalis L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Vetiver</td>
<td>Vetiveria zizanioides Stapf</td>
<td>Do.</td>
</tr>
<tr>
<td>Violet, Swiss</td>
<td>Viola calcarata L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Walnut husks (hull), leaves, and green nuts</td>
<td>Juglans nigra L. or J. regia L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Woodruff, sweet</td>
<td>Asperula odorata L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Yarrow</td>
<td>Achillea millefolium L.</td>
<td>Do.</td>
</tr>
<tr>
<td>Yerba santa</td>
<td>Eriodictyon californicum (Hook. et Arn.) Torr.</td>
<td>Do.</td>
</tr>
<tr>
<td>Yucca, Joshua-tree</td>
<td>Yucca brevifolia Engelm.</td>
<td>Do.</td>
</tr>
<tr>
<td>Yucca, Mohave</td>
<td>Yucca schidigera Roezl ex Ortgies (Y. moavensis Sarg.)</td>
<td>Do.</td>
</tr>
</tbody>
</table>

1 As determined by using the method (or, in other than alcoholic beverages, a suitable adaptation thereof) in section 9.129 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.

58
§ 172.515 Synthetic flavoring substances and adjuvants.

Synthetic flavoring substances and adjuvants may be safely used in food in accordance with the following conditions.

(a) They are used in the minimum quantity required to produce their intended effect, and otherwise in accordance with all the principles of good manufacturing practice.

(b) They consist of one or more of the following, used alone or in combination with flavoring substances and adjuvants generally recognized as safe in food, prior-sanctioned for such use, or regulated by an appropriate section in this part.

Acetal; acetaldehyde diethyl acetol.
Acetaldehyde phenethyl propyl acetol.
Acetanisole; 4-methoxyacetophenone.
Acetophenone; methyl phenyl ketone.
Allyl anthranilate.
Allyl butyrate.
Allyl cinnamate.
Allyl cyclohexaneacetate.
Allyl cyclohexanebutyrate.
Allyl cyclohexanecaproate.
Allyl cyclohexanecaproate.
Allyl cyclohexaneebutyrate.
Allyl dipropionate.
Allyl 2-ethylbutyrate.
Allyl hexanoate; allyl caproate.
Allyl 2,6,6-trimethyl-2-cyclohexene-1-yil-1,2,3,3a,3b,4,5,6,6a,6b,6c-hexahydro-1a-methyl-6-methylylene-cyclobuta[1,2,3,4]dicyclopentene.
2-Butanol.
2-Butanone; methyl ethyl ketone.
Buter acids.
Butter esters.
Butyl acetate.
Butyl acetoacetate.
Butyl alcohol; 1-butanol.
Butyl anthranilate.
Butyl butyrate.
Butyl butyrylactate; lactic acid, butyl ester, butyrate.
Butyl cinnamate.

Amyl heptanoate.
Amyl hexanoate.
Amyl octanoate.
Anisole; methoxybenzene.
Anisylic acetate.
Anisylic alcohol; p-methoxybenzyl alcohol.
Anisylic butyrate
Anisylic formate.
Anisylic phenylacetate.
Anisylic propionate.
Beechwood creosote.
Benzaldehyde dimethyl acetal.
Benzaldehyde glyceryl acetal; 2-phenyl-1,3-dioxolane.
Benzaldehyde propylene glycol acetal; 4-methyl-2-phenyl-1,3-dioxolane.
Benzenethiol; thiophenol.
Benzoin; 2-hydroxy-2-phenylacetophenone.
Benzophenone; diphenylketone.
Benzyll acetate.
Benzyll acetoacetate.
Benzyll alcohol.
Benzyll benzoate.
Benzyll butyl ether.
Benzyll butyrate.
Benzyll cinnamate.
Benzyll 2,3-dimethylcrotonate; benzyl methyl tiglate.
Benzyll disulfide; dibenzyl disulfide.
Benzyll ethyl ether.
Benzyll formate.
3-Benzyll-4-heptanone; benzyl dipropyl ketone.
Benzyll isobutyrate.
Benzyll isovalerate.
Benzyll mercaptan; α-tolueneethiol.
Benzyll methoxyethyl acetal; acetaldehyde benzyl β-methoxyethyl acetal.
Benzyll phenylacetate.
Benzyll propionate.
Benzyll salicylate.
Birch tar oil.
Bornanol; d-camphanol.
Bornyl acetate.
Bornyl formate.
Bornyl isovalerate.
Bornyl valerate.
β-Bourbonene; 1,2,3,3a,3b,4,5,5,6,6a,6b,6c-decahydro-isopropyl-3a-methyl-6-methylene-cyclobuta[1,2,3,4]dicyclopentene.
2-Butanol.
2-Butanone; methyl ethyl ketone.
Butter acids.
Butter esters.
Butyl acetate.
Butyl acetoacetate.
Butyl alcohol; 1-butanol.
Butyl anthranilate.
Butyl butyrate.
Butyl butyrylactate; lactic acid, butyl ester, butyrate.
α-Butylcinnamaldehyde.
Butyl cinnamate.
§ 172.515

Butyl 2-decenoate.
Butyl ethyl malonate.
Butyl formate.
Butyl heptanoate.
Butyl hexanoate.
Butyl p-hydroxybenzoate.
Butyl isobutyrate.
Butyl isovalerate.
Butyl lactate.
Butyl laurate.
Butyl levulinate.
Butyl phenylacetate.
Butyl propionate.
Butyl stearate.
Butyl sulfide.
Butyl 10-undecenoate.
Butyl valerate.

Butyraldehyde.
Cadinene.
Camphene; 2,2-dimethyl-3-methylene-norbornane.
d-Camphor.
Carvacrol; 2-p-cymenol.
Carvacryl ethyl ether; 2-ethoxy-p-cymene.
Carveol; p-mentha-6,8-dien-2-ol.
Caryophyllene.
Caryophyllene alcohol.
Caryophyllene alcohol acetate.
β-Caryophyllene oxide; 1,6-epoxy-p-menth-8-en-2-one.
Carvyl acetate.
Carvyl propionate.
β-Caryophyllene.
Cyclohexaneacetic acid.
Cyclohexaneethyl acetate.
Cyclohexyl acetate.
Cyclohexyl anthranilate.
Cyclohexyl butyrate.
Cyclohexyl cinnamate.
Cyclohexyl formate.
Cyclohexyl isovalerate.
Cyclohexyl propionate.
p-Cymene.
γ-Decalactone; 4-hydroxy-decanoic acid, γ-lactone.
γ-Decalactone; 5-hydroxy-decanoic acid, δ-lactone.
Decanal dimethyl acetal.
1-Decanol; decyl alcohol.
2-Decenal.
3-Decen-2-one; heptylidene acetone.
Decyl acetate.
Decyl butyrate.
Decyl propionate.
Dibenzyl ether.
4,4-Dibutyl-γ-butyrolactone; 4,4-dibutyl-4-hydroxy-butyric acid, γ-lactone.
Dibutyl sebacate.
Diethyl malate.
Diethyl malonate; ethyl malonate.
Diethyl sebacate.
Diethyl succinate.
Diethyl tartrate.
2,5-Diethyltetrahydrofuran.
Dihydrocarveol; 1-menthen-4-ol; 4-terpinenol.
Dihydrocarvone.
Dihydrocarvyl acetate.
m-Dimethoxybenzene.
Decanal dimethyl acetal.
Diethylbutyl acetate.
2,4-Dimethylacetophenone.
α,α-Dimethylbenzyl isobutyrate; phenylidemethylcarbinyl isobutyrate.
2,6-Dimethyl-5-heptenal.
3,7-Dimethyl-1-octanal; tetrahydrogerananiol.
α,α-Dimethylphenethyl acetate; benzyldimethylcarbinyl acetate.
α,α-Dimethylphenethyl alcohol; dimethylbenzyl carbinol.
α,α-Dimethylphenethyl butyrate; benzylidemethylcarbinyl butyrate.
α,α-Dimethylphenethyl formate; benzyldemethylcarbinyl formate.
Dimethyl succinate.
1,3-Diphenyl-2-propanone; dibenzyl ketone.
Delta-Dodecalactone; 5-hydroxydecanoic acid, delta-lactone.
γ-Dodecalactone; 4-hydroxydecanoic acid γ-lactone.
2-Dodecenal.
Estragole.
p-Ethoxybenzaldehyde.
Ethyl acetacetate.
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Ethyl 2-acetyl-3-phenylpropionate; ethylbenzyl acetoacetate.
Ethyl acetoacetate, mixed esters.
Ethyl acrylate.
Ethyl anthranilate.
Ethyl benzoate.
Ethyl benzoylacetate.

α-Ethylbenzyl butyrate; α-phenylpropyl butyrate.

Ethyl brassylate; tridecanedioic acid cyclic ethylene glycol diester; cyclo 1,13-ethylenedioxytridecan-1,13-dione.

2-Ethylbutyl acetate.
2-Ethylbutyraldehyde.
2-Ethylbutyric acid.

Ethyl cinnamate.

Ethyl cyclohexanepropionate.

Ethyl decanoate.

2-Ethylfuran.

Ethyl 2-furanpropionate.

4-Ethylguaiacol; 4-ethyl-2-methoxyphenol.

Ethyl heptanoate.
2-Ethyl-2-heptenal; 2-ethyl-3-butylacrolein.

Ethyl hexanoate.

2,3-Heptanedione; acetyl valeryl.

3-Heptanol.

4-Heptanone; dipropyl ketone.

cis-4-Heptenal; cis-4-hepten-1-ol.

Heptyl acetate.

Heptyl alcohol; enanthic alcohol.

Heptyl butyrate.

Heptyl cinnamate.

Heptyl formate.

Heptyl isobutyrate.

Heptyl octanoate.

1-Hexadecanol; cetyl alcohol.

ω-6-Hexadecenolactone; 16-hydroxy-6-hexadecenoic acid, ω-lactone; ambrettolide.

γ-Hexalactone; 4-hydroxyhexanoic acid, γ-lactone; tonkalide.

Hexanal; caproic aldehyde.

2,3-Hexanediol; acetyl butyryl.

Hexanoic acid; caproic acid.

2-Hexenal.

2-Hexen-1-ol.

3-Hexen-1-ol; leaf alcohol.

2-Hexen-1-yl acetate.

3-Hexenyl isovalerate.

3-Hexenyl 2-methylbutyrate.

3-Hexenyl phenylacetate; cis-3-hexenyl phenylacetate.

Hexyl acetate.

2-Hexyloxytetrahydropyran.

Hexyl alcohol.

Hexyl butyrate.

α-Hexylcinnamaldehyde.

Hexyl formate.

Hexyl hexanoate.

2-Hexylidene cyclopentanone.
Hexyl isoamylate.
Hexyl 2-methylbutyrate.
Hexyl octanoate.
Hexyl phenylacetate; n-hexyl phenylacetate.
Hexyl propionate.
Hydroxycitronellal; 3,7-dimethyl-7-hydroxyoctanal.
Hydroxycitronellal diethyl acetal.
Hydroxycitronellal dimethyl acetal.
Hydroxycitronellol; 3,7-dimethyl-1,7-octanediol.
N-(4-Hydroxy-3-methoxybenzyl)-nonanamide; pelargonyl vanillylamide.
5-Hydroxy-4-octanone; butyroin.
4-[(p-Hydroxyphenyl)-2-butanone; p-hydroxybenzyl acetone.
Indole.
α-ionone; 4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one.
β-ionone; 4-(2,6,6-trimethyl-1-cyclohexen-1-yl)-3-buten-2-one.
α-lone; 4-(2,5,5,6-tetramethyl-2-cyclohexene-1-yl)-3-buten-2-one; 6-methylionone.
Isoamyl acetate.
Isoamyl acetoacetate.
Isoamyl alcohol; isopentyl alcohol; 3-methyl-1-butanol.
Isoamyl benzoate.
Isoamyl butyrate.
Isoamyl cinnamate.
Isoamyl formate.
Isoamyl 2-furanpropionate; α-isomethyl furfurylpropionate.
Isoamyl 2-furanpropionate; α-isomethyl furfurylacetate.
Isoamyl hexanoate.
Isoamyl isovalerate.
Isoamyl laurate.
Isoamyl-2-methylbutyrate; isopentyl-2-methylbutyrate.
Isoamyl nonanoate.
Isoamyl octanoate.
Isoamyl phenylacetate.
Isoamyl propionate.
Isoamyl pyruvate.
Isoamyl salicylate.
Isoborneol.
Isobornyl acetate.
Isobornyl formate.
Isobornyl isovalerate.
Isobornyl propionate.
Isobutyl acetate.
Isobutyl acetoacetate.
Isobutyl alcohol.
Isobutylangelate; isobutyl cis-2-methyl-2-butenoate.
Isobutylanthranilate.
Isobutylbenzoate.
Isobutylbutyrate.
Isobutylcinnamate.
Isobutylformate.
Isobutyl2-furanpropionate.
Isobutylheptanoate.
Isobutylhexanoate.
Isobutylisobutyrate.
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Myrcene; 7-methyl-3-methylene-1,6-octadiene.
Myristaldehyde; tetradecanal.
d-Neomenthol; 2-isopropyl-5-methylcyelo-
hexanol.
Nerol; cis-3,7-dimethyl-2,6-octadien-1-ol.
Nerolidol; 3,7,11-trimethyl-1,6,10-dodecatren-
3-ol.
Neryl acetate.
Neryl butyrate.
Neryl formate.
Neryl isobutyrate.
Neryl isovalerate.
Neryl propionate.
2,6-Nonadien-1-ol.
γ-Nonalactone; 4-hydroxynonanoic acid, γ-
lactone; aldehyde C–18.
Nonanal; pelargonic aldehyde.
1,3-Nonanediol acetate, mixed esters.
Nonanoic acid; pelargonic acid.
2-Nonanone; methylheptyl ketone.
3-Nonanon-1-yl acetate; 1-hydroxy-3-
nonanone acetate.
Nonyl acetate.
Nonyl alcohol; 1-nonanol.
Nonyl octanoate.
Nonyl isovalerate.
Nooxkatone; 5,6-dimethyl-8-isopropenyl-
bicyclo[4,4,0]-dec-1-en-3-one.
Ocimene; trans-β-ocimene; 3,7-dimethyl-1,3,6-
ocatriene.
γ-Octalactone; 4-hydroxyoctanoic acid, γ-lac-
tone.
Octanal; caprylaldehyde.
Octanal dimethyl acetate.
1-Octanol; octyl alcohol.
2-Octanol.
3-Octanol.
2-Octanone; methyl hexyl ketone.
3-Octanone; ethyl amyl ketone.
2-Octanone-1-ol.
1-Octen-3-ol; amyl vinyl carbinol.
1-Octen-3-yl acetate.
Octyl acetate.
3-Octyl acetate.
Octyl butyrate.
Octyl formate.
Octyl heptanoate.
Octyl isobutyrate.
Octyl isovalerate.
Octyl octanoate.
Octyl phenylacetate.
Octyl propionate.
α-Pentadecalactone; 15-hydroxypentadeca-
nolic acid, α-lactone; pentadecanolide; an-
gelica lactone.
2,3-Pentanedione; acetyl propionyl.
2-Pentanone; methyl propyl ketone.
4-Pentenoic acid.
1-Penten-3-ol.
Perillaldehyde; 4-isopropenyl-1-cyclohexene-
1-carboxaldehyde.; p-mentha-1,8-dien-7-al.
Perillyl acetate; p-mentha-1,8-dien-7-y acet-
tate.
α-Phellandrene; p-mentha-1,5-diene.
Phenethyl acetate.
Phenethyl alcohol; β-phenylethyl alcohol.
Phenethyl anthranilate.
Phenethyl benzoate.
Phenethyl butyrate.
Phenethyl cinnamate.
Phenethyl formate.
Phenethyl isobutyrate.
Phenethyl isovalerate.
Phenethyl 2-methylbutyrate.
Phenethyl phenylacetate.
Phenethyl propionate.
Phenethyl salicylate.
Phenethyl senecioate; phenethyl 3,3-di-
methylacrylate.
Phenethyl tiglate.
Phenoxyacetic acid.
2-Phenoxyethyl isobutyrate.
Phenyacetyledehyde; α-toluic aldehyde.
Phenylacetaldheyde 2,3-butylene glycol ace-
tal.
Phenylacetaldheyde dimethyl acetal.
Phenylacetaldheyde glyceryl acetal.
Phenylacetic acid; α-toluic acid.
4-Phenyl-2-butanol; phenylethyl methyl car-
binol.
4-Phenyl-3-buten-2-ol; methyl styryl car-
binol.
4-Phenyl-3-buten-2-one.
4-Phenyl-2-butyrate acetate; phenylethyl meth-
yl carbinyl acetate.
1-Phenyl-3-methyl-3-pentanol; phenylethyl methyl ethyl carbinol.
1-Phenyl-1-propanol; phenylethyl carbinol.
3-Phenyl-1-propanol; hydrocinnamyl alcohol.
2-Phenylproplonaldehyde; hydratropalde-
hyde.
3-Phenylproplonaldehyde; hydrocinnamal-
dehyde.
2-Phenylproplonaldehyde dimethyl acetal; 
hydratropic aldehyde dimethyl acetal.
3-Phenylproplonalacetic acid; hydrocinnamic acid.
3-Phenylpropyl acetate.
2-Phenylpropyl butyrate.
3-Phenylpropyl cinnamate.
3-Phenylpropyl formate.
3-Phenylpropyl hexanoate.
2-Phenylpropyl isobutyrate.
3-Phenylpropyl isovalurate.
3-Phenylpropyl isovalerate.
3-Phenylpropyl propionate.
2-(3-Phenylpropyl)tetrahydrofuran.
α-Pinene; 2-pinene.
β-Pinene; 2(10)-pinene.
Pine tar oil.
Pinocarveol; 2(10)-pinen-3-ol.
Piperidine.
Piperine.
d-Piperitone; p-menth-1-en-3-one.
Piperitenone; p-menth-1,4(8)-dien-3-one.
Piperitene oxide; 1,2-epoxy-p-menth-4(8)-
en-3-one.
Piperonly acetate; heliotropyl acetate.
Piperonly isobutyrate.
Polyisomone.
Polysorbate 20; polyoxyethylene (20) sorbitan monolaurate.
Polysorbate 60; polyoxyethylene (20) sorbitan monostearate.
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§ 172.520 Cocoa with dioctyl sodium sulfosuccinate for manufacturing.

The food additive “cocoa with dioctyl sodium sulfosuccinate for manufacturing,” conforming to §163.117 of this chapter, is used in the manufacture of cocoa products in the following combinations and concentrations:

- Tetramethyl ethylcyclohexene nonone; mixture of 5-ethyl-2,3,4,5-tetramethyl-2-cyclohexen-1-one and 5-ethyl-3,4,5,6-tetramethyl-2-cyclohexen-1-one.
- 2-Thiencyl mercaptan; 2-thiencylthiol.
- Thymol.
- Tolualdehyde glyceryl acetal, mixed o, m, p.
- Tolualdehydes, mixed o, m, p.
- p-Tolylacetate.
- p-Tolyl acetate; o-cresyl acetate.
- p-Tolyl acetate; p-cresyl acetate.
- 4-(p-Tolyl)-2-butanone; p-methylbenzaldehyde.
- p-Tolyl isobutyrate.
- p-Tolyl laurate.
- p-Tolyl phenylacetate.
- 2-(p-Tolyl)-propionaldehyde; p-methylhydrocinnamic aldehyde.
- Tributyl acetyl citrate.
- 2-Undecenal.
- 2.3-Undecadiene; acetyl nonryl.
- 3-Undecanone; 4-hydroxyundecanoic acid γ-lactone; peach aldehyde; aldehyde C–14.
- Undecenal.
- 2-Undecanone; methyl nonyl ketone.
- 9-Undecenal; undecenoic aldehyde.
- 10-Undecenal.
- Undecen-1-al; undecylenic alcohol.
- 10-Undecen-1-yl acetate.
- Undecyl alcohol.
- Valeraldehyde; pentanal.
- Valeric acid; pentanoic acid.
- Vanillin acetate; acetyl vanillin.
- Veratraldehyde.
- Verbenol; 2-pinen-4-ol.
- Zingerone; 4-(4-hydroxy-3-methoxyphenyl)-2-butanone.

(c) Δ-Decalactone and Δ-dodecalactone when used separately or in combination in oleomargarine are used at levels not to exceed 5 parts per million and 20 parts per million, respectively, in accordance with §166.110 of this chapter.

(d) BHA (butylated hydroxyanisole) may be used as an antioxidant in flavoring substances whereby the additive does not exceed 0.5 percent of the essential (volatile) oil content of the flavoring substance.


§ 172.520 Cocoa with dioctyl sodium sulfosuccinate for manufacturing.

The food additive “cocoa with dioctyl sodium sulfosuccinate for manufacturing,” conforming to §163.117 of this chapter, is used in the manufacture of cocoa products in the following combinations and concentrations:
§ 172.530 Disodium guanylate.

Disodium guanylate may be safely used as a flavor enhancer in foods, at a level not in excess of that reasonably required to produce the intended effect.

§ 172.535 Disodium inosinate.

The food additive disodium inosinate may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the disodium salt of inosinic acid, manufactured and purified so as to contain no more than 150 parts per million of soluble barium in the compound disodium inosinate with seven and one-half molecules of water of crystallization.

(b) The food additive is used as a flavoring adjuvant in food.

§ 172.540 DL-Alanine.

DL-Alanine (a racemic mixture of D- and L-alanine; CAS Reg. No. 302–72–7) may be safely used as a flavor enhancer for sweeteners in pickling mixtures at a level not to exceed 1 percent of the pickling spice that is added to the pickling brine.

§ 172.550 Modified hop extract.

The food additive modified hop extract may be safely used in beer in accordance with the following prescribed conditions:

(a) The food additive is used or intended for use as a flavoring agent in the brewing of beer.

(b) The food additive is manufactured by one of the following processes:

(1) The additive is manufactured from a hexane extract of hops by simultaneous isomerization and selective reduction in an alkaline aqueous medium with sodium borohydride, whereby the additive meets the following specifications:

(i) A solution of the food additive solids is made up in approximately 0.012 n alkaline methyl alcohol (6 milliliters of 1 n sodium hydroxide diluted to 500 milliliters with methyl alcohol) to show an absorbance at 253 millimicrons of 0.6 to 0.9 per centimeter. (This absorbance is obtained by approximately 0.03 milligram solids permilliliter.) The ultraviolet absorption spectrum of this solution exhibits the following characteristics: An absorption peak at 253 millimicrons; no absorption peak at 325 to 330 millimicrons; the absorbance at 268 millimicrons does not exceed the absorbance at 272 millimicrons.

(ii) The boron content of the food additive does not exceed 310 parts per million (0.0310 percent), calculated as boron.

(2) The additive is manufactured from hops by a sequence of extractions and fractionations, using benzene, light petroleum spirits, and methyl alcohol as solvents, followed by isomerization by potassium carbonate treatment. Residues of solvents in the modified hop extract shall not exceed 1.0 part per million of benzene, 1.0 part per million of light petroleum spirits, and 250 parts per million of methyl alcohol. The light petroleum spirits and benzene solvents shall comply with the specifications in § 172.250 except that the boiling point range for light petroleum spirits is 150 °F–300 °F.

(3) The additive is manufactured from hops by a sequence of extractions and fractionations, using methylene chloride, hexane, and methyl alcohol as solvents, followed by isomerization by sodium hydroxide treatment. Residues of the solvents in the modified hop extract shall not exceed 5 parts per million of methylene chloride, 25 parts per million of hexane, and 100 parts per million of methyl alcohol.

(4) The additive is manufactured from hops by a sequence of extractions and fractionations, using benzene, light petroleum spirits, methyl alcohol, n-buty alcohol, and ethyl acetate as solvents, followed by isomerization by potassium carbonate treatment. Residues of solvents in the modified hop extract shall not exceed 1.0 part per million of benzene, 1.0 part per million of light petroleum spirits, 50 parts per million of methyl alcohol, 50 parts per million
of \( n \)-butyl alcohol, and 1 part per million of ethyl acetate. The light petroleum spirits and benzene solvents shall comply with the specifications in §172.250 except that the boiling point range for light petroleum spirits is 150 °F to 300 °F.

(5) The additive is manufactured from hops by an initial extraction and fractionation using one or more of the following solvents: Ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene, and water; followed by isomerization by calcium chloride or magnesium chloride treatment in ethylene dichloride, methylene chloride, or trichloroethylene and a further sequence of extractions and fractionations using one or more of the solvents set forth in this paragraph. Residues of the solvents in the modified hop extract shall not exceed 125 parts per million of hexane; 150 parts per million of ethylene dichloride, methylene chloride, or trichloroethylene; or 250 parts per million of isopropyl alcohol or methyl alcohol.

(6) The additive is manufactured from hops by an initial extraction and fractionation using one or more of the solvents listed in paragraph (b)(5) of this section followed by: Hydrogenation using palladium as a catalyst in methyl alcohol, ethyl alcohol, or isopropyl alcohol acidified with hydrochloric or sulfuric acid; oxidation with peracetic acid; isomerization by calcium chloride or magnesium chloride treatment in ethylene dichloride, methylene chloride, or trichloroethylene (alternatively, the hydrogenation and isomerization steps may be performed in reverse order); and a further sequence of extractions and fractionations using one or more of the solvents listed in paragraph (b)(5) of this section. The additive shall meet the residue limitations as prescribed in paragraph (b)(5) of this section.

(7) The additive is manufactured from hops as set forth in paragraph (b)(6) of this section followed by reduction with sodium borohydride in aqueous alkaline methyl alcohol, and a sequence of extractions and fractionations using one or more of the solvents listed in paragraph (b)(5) of this section. The additive shall meet the residue limitations as prescribed in paragraph (b)(5) of this section, and a boron content level not in excess of 300 parts per million (0.0300 percent), calculated as boron.

(8) The additive is manufactured from hops as a nonisomerizable nonvolatile hop resin by an initial extraction and fractionation using one or more of the solvents listed in paragraph (b)(5) of this section followed by a sequence of aqueous extractions and removal of nonaqueous solvents to less than 0.5 percent. The additive is added to the wort before or during cooking in the manufacture of beer.

§ 172.575 Quinine.

Quinine, as the hydrochloride salt or sulfate salt, may be safely used in food in accordance with the following conditions:

<table>
<thead>
<tr>
<th>Uses</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>In carbonated beverages as a flavor.</td>
<td>Not to exceed 83 parts per million, as quinine. Label shall bear a prominent declaration of the presence of quinine either by the use of the word “quinine” in the name of the article or through a separate declaration.</td>
</tr>
</tbody>
</table>

§ 172.580 Safrole-free extract of sassafras.

The food additive safrole-free extract of sassafras may be safely used in accordance with the following prescribed conditions:

(a) The additive is the aqueous extract obtained from the root bark of the plant *Sassafras albidum* (Nuttall) Nees (Fam. Lauraceae).

(b) It is obtained by extracting the bark with dilute alcohol, first concentrating the alcoholic solution by vacuum distillation, then diluting the concentrate with water and discarding the oily fraction.

(c) The purified aqueous extract is safrole-free.

(d) It is used as a flavoring in food.

§ 172.585 Sugar beet extract flavor base.

Sugar beet extract flavor base may be safely used in food in accordance with the provisions of this section.

(a) Sugar beet extract flavor base is the concentrated residue of soluble sugar beet extractives from which
§ 172.590  Yeast-malt sprout extract.

Yeast-malt sprout extract, as described in this section, may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is produced by partial hydrolysis of yeast extract (derived from Saccharomyces cerevisiae, Saccharomyces fragilis, or Candida utilis) using the sprout portion of malt barley as the source of enzymes. The additive contains a maximum of 6 percent 5′ nucleotides by weight.

(b) The additive may be used as a flavor enhancer in food at a level not in excess of that reasonably required to produce the intended effect.

Subpart G—Gums, Chewing Gum Bases and Related Substances

§ 172.610  Arabinogalactan.

Arabinogalactan may be safely used in food in accordance with the following conditions:

(a) Arabinogalactan is a polysaccharide extracted by water from Western larch wood, having galactose units and arabinose units in the approximate ratio of six to one.

(b) It is used in the following foods in the minimum quantity required to produce its intended effect as an emulsifier, stabilizer, binder, or bodying agent: Essential oils, nonnutritive sweeteners, flavor bases, nonstandardized dressings, and pudding mixes.

§ 172.615  Chewing gum base.

The food additive chewing gum base may be safely used in the manufacture of chewing gum in accordance with the following prescribed conditions:

(a) The food additive consists of one or more of the following substances that meet the specifications and limitations prescribed in this paragraph, used in amounts not to exceed those required to produce the intended physical or other technical effect.
### Masticatory Substances—Continued

#### Natural (Coagulated or Concentrated Latices) of Vegetable Origin

<table>
<thead>
<tr>
<th>Family</th>
<th>Genus and species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Natural rubber (smoked sheet and latex solids)</td>
<td>Hevea brasiliensis.</td>
</tr>
</tbody>
</table>

#### Synthetic

| Specifications | | |
|----------------|-----------------|
| Butadiene-styrene rubber | Basic polymer. |
| Isobutylene-isoprene copolymer (butyl rubber) | Synthesized by Fischer-Tropsch process from carbon monoxide and hydrogen which are catalytically converted to a mixture of paraffin hydrocarbons. Lower molecular weight fractions are removed by distillation. The residue is hydrogenated and further treated by percolation through activated charcoal. The product has a congealing point of 93 °C–99 °C as determined by ASTM method D908–71 (Reapproved 1981), “Standard Test Method for Congealing Point of Petroleum Waxes, Including Petroleum,” a maximum oil content of 0.5 percent as determined by ASTM method D721–56T, “Tentative Method of Test for Oil Content of Petroleum Waxes,” and an absorptivity of less than 0.01 at 290 millimicrons in decachloronaphthalene at 88 °C as determined by ASTM method D2008–80, “Standard Test Method for Ultraviolet Absorbance and Absorptivity of Petroleum Products,” which are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, 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](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). |
| Paraffin | Complying with § 172.886. |

#### Plasticizing Materials (Softeners)

| Petroleum wax | Complying with § 172.886. |
| Petroleum wax synthetic | Complying with § 172.886. |
| Polyethylene | Molecular weight 2,000–21,000. |
| Polyisobutylene | Minimum molecular weight 37,000 (Flory). |
| Polynvinyl acetate | Molecular weight, minimum 2,000. |

#### Terpene Resins

| Synthetic resin | Consisting of polymers of α-pinene, β-pinene, and/or dipentene; acid value less than 5, saponification number less than 5, and color less than 4 on the Gardner scale as measured in 50 percent mineral spirit solution. |
§ 172.620 Carrageenan.

The food additive carrageenan may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the refined hydrocolloid prepared by aqueous extraction from the following members of the families Gigartinaceae and Solieriacae of the class Rodophyceae (red seaweed):

Chondrus crispus.
Chondrus ocellatus.
Eucheuma cottonii.
Eucheuma spinosum.
Gigartina acicularis.
Gigartina pistillata.
Gigartina radula.
Gigartina stellata.

(b) The food additive conforms to the following conditions:

(1) It is a sulfated polysaccharide the dominant hexose units of which are galactose and anhydrogalactose.

(2) Range of sulfate content: 20 percent to 40 percent on a dry-weight basis.

(c) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the additive, carrageenan.

§ 172.623 Carrageenan with polysorbate 80.

Carrageenan otherwise meeting the definition and specifications of § 172.620 (a) and (b) and salts of carrageenan otherwise meeting the definition of § 172.626(a) may be safely produced with the use of polysorbate 80 meeting the specifications and requirements of § 172.840 (a) and (b) in accordance with the following prescribed conditions:

(a) The polysorbate 80 is used only to facilitate separation of sheeted carrageenan and salts of carrageenan from drying rolls.

(b) The carrageenan and salts of carrageenan contain not more than 5 percent by weight of polysorbate 80, and the final food containing the additives contains polysorbate 80 in an amount not to exceed 500 parts per million.

(c) The carrageenan and salts of carrageenan so produced are used only in producing foods in gel form and only for the purposes defined in §§172.620(c) and 172.626(b), respectively.
(d) The carrageenan and salts of carrageenan so produced are not used in foods for which standards of identity exist unless the standards provide for the use of carrageenan, or salts of carrageenan, combined with polysorbate 80.

(e) The carrageenan and salts of carrageenan produced in accordance with this section, and foods containing the same, in addition to the other requirements of the Act, are labeled to show the presence of polysorbate 80, and the label or labeling of the carrageenan and salts of carrageenan so produced bear adequate directions for use.

§ 172.626 Salts of carrageenan.

The food additive salts of carrageenan may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive consists of carrageenan, meeting the provisions of §172.620, modified by increasing the concentration of one of the naturally occurring salts (ammonium, calcium, potassium, or sodium) of carrageenan to the level that it is the dominant salt in the additive.

(b) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the salt of carrageenan that dominates the mixture by reason of the modification, e.g., “sodium carrageenan”, “potassium carrageenan”, etc.

§ 172.655 Furcelleran.

The food additive furcelleran may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the refined hydrocolloid prepared by aqueous extraction of furcellaria fastigiata of the class Rodophyceae (red seaweed).

(b) The food additive conforms to the following:

(1) It is a sulfated polysaccharide the dominant hexose units of which are galactose and anhydrogalactose.

(2) Range of sulfate content: 8 percent to 19 percent, on a dry-weight basis.

(c) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the additive, furcelleran.

§ 172.660 Salts of furcelleran.

The food additive salts of furcelleran may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive consists of furcelleran, meeting the provisions of §172.655, modified by increasing the concentration of one of the naturally occurring salts (ammonium, calcium, potassium, or sodium) of furcelleran to the level that it is the dominant salt in the additive.

(b) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the salt of furcelleran that dominates the mixture by reason of the modification, e.g., “sodium furcelleran”, “potassium furcelleran”, etc.

§ 172.665 Gellan gum.

The food additive gellan gum may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a high molecular weight polysaccharide gum produced from Pseudomonas elodea by a pure culture fermentation process and purified by recovery with isopropyl alcohol. It is composed of tetrasaccharide repeat units, each containing one molecule of rhamnose and glucuronic acid, and two molecules of glucose. The glucuronic acid is neutralized to a mixed potassium, sodium, calcium, and magnesium salt. The polysaccharide may contain acyl (glyceryl and acetyl) groups as the O-glycosidically linked esters.
(b) The strain of *P. elodea* is non-pathogenic and nontoxic in man and animals.

(c) The additive is produced by a process that renders it free of viable cells of *P. elodea*.

(d) The additive meets the following specifications:

1. Positive for gellan gum when subjected to the following identification tests:
   - A 1-percent solution is made by hydrating 1 gram of gellan gum in 99 milliliters of distilled water. The mixture is stirred for about 2 hours, using a motorized stirrer and a propeller-type stirring blade. A small amount of the above solution is drawn into a wide bore pipet and transferred into a solution of 10-percent calcium chloride. A tough worm-like gel will form instantly.
   - To the 1-percent distilled water solution prepared for identification test (i), 0.50 gram of sodium chloride is added. The solution is heated to 80 °C with stirring, held at 80 °C for 1 minute, and allowed to cool to room temperature without stirring. A firm gel will form.

2. Residual isopropyl alcohol (IPA) not to exceed 0.075 percent as determined by the procedure described in the Xanthan Gum monograph, the “Food Chemicals Codex,” 4th ed. (1996), pp. 437–438, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address http://www.nap.edu), or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 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.

(e) The additive is used or intended for use in accordance with current good manufacturing practice as a stabilizer and thickener as defined in §170.3(o)(28) of this chapter. The additive may be used in foods where standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use.

(f) To assure safe use of the additive:

1. The label of its container shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the name of the additive and the designation “food grade”.

2. The label or labeling of the food additive container shall bear adequate directions for use.


§ 172.695 Xanthan gum.

The food additive xanthan gum may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a polysaccharide gum derived from *Xanthomonas campestris* by a pure-culture fermentation process and purified by recovery with isopropyl alcohol. It contains D-glucose, D-mannose, and D-glucuronic acid as the dominant hexose units and is manufactured as the sodium, potassium, or calcium salt.

(b) The strain of *Xanthomonas campestris* is nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that renders it free of viable cells of *Xanthomonas campestris*.

(d) The additive meets the following specifications:

1. Positive for xanthan gum when subjected to the following procedure:
   - Blend on a weighing paper or in a weighing pan 1.0 gram of powdered locust bean gum with 1.0 gram of the powdered polysaccharide

   **LOCUST BEAN GUM GEL TEST**

   Blend on a weighing paper or in a weighing pan 1.0 gram of powdered locust bean gum with 1.0 gram of the powdered polysaccharide
to be tested. Add the blend slowly (approximately 1/2 minute) at the point of maximum agitation to a stirred solution of 200 milliliters of distilled water previously heated to 80 °C in a 400-milliliter beaker. Continue mechanical stirring until the mixture is in solution, but stir for a minimum time of 30 minutes. Do not allow the water temperature to drop below 60 °C.

Set the beaker and its contents aside to cool in the absence of agitation. Allow a minimum time of 2 hours for cooling. Examine the cooled beaker contents for a firm rubbery gel formation after the temperature drops below 40 °C.

In the event that a gel is obtained, make up a 1 percent solution of the polysaccharide to be tested in 200 milliliters of distilled water previously heated to 80 °C (omit the locust bean gum). Allow the solution to cool without agitation as before. Formation of a gel on cooling indicates that the sample is a gelling polysaccharide and not xanthan gum.

Record the sample as ‘‘positive’’ for xanthan gum if a firm, rubbery gel forms in the presence of locust bean gum but not in its absence. Record the sample as ‘‘negative’’ for xanthan gum if no gel forms or if a soft or brittle gel forms both with locust bean gum and in a 1 percent solution of the sample (containing no locust bean gum).

(4) Positive for xanthan gum when subjected to the following procedure:

**PYRUVIC ACID TEST**

Pipet 10 milliliters of an 0.6 percent solution of the polysaccharide in distilled water (60 milligrams of water-soluble gum) into a 50-milliliter flask equipped with a standard taper glass joint. Pipet in 20 milliliters of 1N hydrochloric acid. Weigh the flask. Reflux the mixture for 3 hours. Take precautions to avoid loss of vapor during the refluxing. Cool the solution to room temperature. Add distilled water to make up any weight loss from the flask contents.

Pipet 1 milliliter of a 2,4-dinitrophenyl-hydrazine reagent (0.5 percent in 2N hydrochloric acid) into a 30-milliliter separatory funnel followed by a 2-milliliter aliquot (4 milligrams of water-soluble gum) of the polysaccharide hydrolyzate. Mix and allow the reaction mixture to stand at room temperature for 5 minutes. Extract the mixture with 5 milliliters of ethyl acetate. Discard the aqueous layer.

Extract the hydrazone from the ethyl acetate with three 5 milliliter portions of 10 percent sodium carbonate solution. Dilute the combined sodium carbonate extracts to 100 milliliters with additional 10 percent sodium carbonate in a 10-milliliter volumetric flask. Measure the optical density of the sodium carbonate solution at 395 millimicrons.

Compare the results with a curve of the optical density versus concentration of an authentic sample of pyruvic acid that has been run through the procedure starting with the preparation of the hydrazone.

Record the percent by weight of pyruvic acid in the test polysaccharide. Note ‘‘positive’’ for xanthan gum if the sample contains more than 1.5 percent of pyruvic acid and ‘‘negative’’ for xanthan gum if the sample contains less than 1.5 percent of pyruvic acid by weight.

(e) The additive is used or intended for use in accordance with good manufacturing practice as a stabilizer, emulsifier, thickener, suspending agent, bodying agent, or foam enhancer in foods for which standards of identity established under section 401 of the Act do not preclude such use.

(f) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to other information required by the Act, the name of the additive and the designation ‘‘food grade’’.

(2) The label or labeling of the food additive container shall bear adequate directions for use.

**Subpart H—Other Specific Usage Additives**

§ 172.710 Adjuvants for pesticide use dilutions.

The following surfactants and related adjuvants may be safely added to pesticide use dilutions by a grower or applicant prior to application to the growing crop:

- Alkyl (C₈-C₁₆) amine acetate, where the alkyl groups (C₈-C₁₆) are derived from coconut oil, as a surfactant in emulsifier blends at levels not in excess of 5 percent by weight of the emulsifier blends that are added to herbicides for application to corn and sorghum.

- Di-n-alkyl (C₈-C₁₆) dimethyl ammonium chloride, where the alkyl groups (C₈-C₁₆) are derived from coconut oil, as surfactants in emulsifier blends at levels not in excess of 5 percent by weight of emulsifier blends that are added to herbicides for application to corn or sorghum.

Diethanolamide condensate based on a mixture of saturated and unsaturated soybean oil fatty acids (C₁₀-C₁₈) as a surfactant in emulsifier blends that are added to the herbicide atrazine for application to corn.

Diethanolamide condensate based on stripped coconut fatty acids (C₁₀-C₁₈) as a surfactant in emulsifier blends that are
added to the herbicide atrazine for application to corn.

$\alpha$-(p-Dodecylphenyl)-omega-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of dodecylphenol (dodecyl group is a propylene tetramer isomer) with an average of 4–14 or 30–70 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4–14 or 30–70.

Ethylene dichloride.

Polyglyceryl phthalate ester of coconut oil fatty acids.

$\alpha$-\([p-(1,1,3,3-\text{tetramethylbutyl})\text{phenyl}]-\omega\)-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of $p$-(1,1,3,3-tetramethylbutyl) phenol with an average of 4–14 or 30–70 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4–14 or 30–70.

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.

§ 172.712 1,3-Butylene glycol.

The food additive 1,3-butylene glycol (CAS Reg. No. 107–88–0) may be safely used in food in accordance with the following prescribed conditions:

(a) It is prepared by the aldol condensation of acetaldehyde followed by catalytic hydrogenation.

(b) The food additive shall conform to the identity and specifications listed in the monograph entitled “1,3-Butylene Glycol” in the Food Chemicals Codex, 4th ed. (1996), p. 52, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 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.

(c) It is used in the manufacture of sausage casings as a formulation aid as defined in §170.3(o)(14) of this chapter and as a processing aid as defined in §170.3(o)(24) of this chapter.


§ 172.715 Calcium lignosulfonate.

Calcium lignosulfonate may be safely used in or on food, subject to the provisions of this section.

(a) Calcium lignosulfonate consists of sulfonated lignin, primarily as calcium and sodium salts.

(b) It is used in an amount not to exceed that reasonably required to accomplish the intended physical or technical effect when added as a dispersing agent and stabilizer in pesticides for preharvest or postharvest application to bananas.

§ 172.720 Calcium lactobionate.

The food additive calcium lactobionate may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the calcium salt of lactobionic acid (4-(\(\beta,D\rceil\)-galactosido)-\(D\rceil\)-gluconic acid) produced by the oxidation of lactose.

(b) It is used or intended for use as a firming agent in dry pudding mixes at a level not greater than that required to accomplish the intended effect.

§ 172.723 Epoxidized soybean oil.

Epoxidized soybean oil may be safely used in accordance with the following prescribed conditions:

(a) The additive is prepared by reacting soybean oil in toluene with hydrogen peroxide and formic acid.

(b) It meets the following specifications:

(1) Epoxidized soybean oil contains oxirane oxygen, between 7.0 and 8.0 percent, as determined by the American Oil Chemists’ Society (A.O.C.S.) method Cd 9–57, “Oxirane Oxygen,” reapproved 1989, which is incorporated by reference in accordance with 5 U.S.C
§ 172.725 Gibberellic acid and its potassium salt.

The food additives gibberellic acid and its potassium salt may be used in the malting of barley in accordance with the following prescribed conditions:

(a) The additives meet the following specifications:

(1) The gibberellic acid is produced by deep-culture fermentation of a suitable nutrient medium by a strain of Fusarium moniliforme or a selection of this culture.

(2) The gibberellic acid produced is of 80 percent purity or better.

(3) The empirical formula of gibberellic acid is represented by $\text{C}_{19}\text{H}_{22}\text{O}_6$.

(4) Potassium gibberellate is the potassium salt of the specified gibberellic acid.

(5) The potassium gibberellate is of 80 percent purity or better.

(6) The gibberellic acid or potassium gibberellate may be diluted with substances generally recognized as safe in foods or with salts of fatty acids conforming to §172.863.

(b) They are used or intended for use in the malting of barley under conditions whereby the amount of either or both additives present in the malt is not in excess of 2 parts per million expressed as gibberellic acid, and the treated malt is to be used in the production of fermented malt beverages or distilled spirits only, whereby the finished distilled spirits contain none and the finished malt beverage contains not more than 0.5 part per million of gibberellic acid.

(c) To insure the safe use of the food additives the label of the package shall bear, in addition to the other information required by the Act:

(1) The name of the additive, “gibberellic acid” or “potassium gibberellate”, whichever is appropriate.

(2) An accurate statement of the concentration of the additive contained in the package.

(3) Adequate use directions to provide not more than 2 parts per million of gibberellic acid in the finished malt.

(4) Adequate labeling directions to provide that the final malt is properly...
§ 172.730 Potassium bromate.

The food additive potassium bromate may be safely used in the malting of barley under the following prescribed conditions:

(a)(1) It is used or intended for use in the malting of barley under conditions whereby the amount of the additive present in the malt from the treatment does not exceed 75 parts per million of bromate (calculated as Br), and the treated malt is used only in the production of fermented malt beverages or distilled spirits.

(b) The total residue of inorganic bromides in fermented malt beverages, resulting from the use of the treated malt plus additional residues of inorganic bromides that may be present from uses in accordance with other regulations in this chapter promulgated under sections 408 and/or 409 of the act, does not exceed 25 parts per million of bromide (calculated as Br). No tolerance is established for bromide in distilled spirits because there is evidence that inorganic bromides do not pass over in the distillation process.

(b) To assure safe use of the additive, the label or labeling of the food additive shall bear, in addition to the other information required by the Act, the following:

(1) The name of the additive.

(2) Adequate directions for use.

(c) To assure safe use of the additive, the label or labeling of the treated malt shall bear, in addition to other information required by the Act, the statement, “Brewer’s Malt—To be used in the production of fermented malt beverages only,” or “Distiller’s Malt—To be used in the production of distilled spirits only,” whichever is the case.

§ 172.735 Glycerol ester of rosin.

Glycerol ester of wood rosin, gum rosin, or tall oil rosin may be safely used in food in accordance with the following prescribed conditions:

(a) It has an acid number of 3 to 9, a drop-softening point of 88 to 96 °C; and a color of N or paler as determined in accordance with Official Naval Stores Standards of the United States. It is purified by countercurrent steam distillation or steam stripping.

(b) It is used to adjust the density of citrus oils used in the preparation of beverages whereby the amount of the additive does not exceed 100 parts per million of the finished beverage.


§ 172.736 Glycerides and polyglycides of hydrogenated vegetable oils.

The food additive glycerides and polyglycides of hydrogenated vegetable oils may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is manufactured by heating a mixture of hydrogenated oils of vegetable origin and polyethylene glycol in the presence of an alkaline catalyst followed by neutralization with any acid that is approved or is generally recognized as safe for this use to yield the finished product.

(b) The additive consists of a mixture of mono-, di- and tri-glycerides and polyethylene glycol mono- and diesters of fatty acids (polyglycides) of hydrogenated vegetable oils and meets the following specifications:

552(a) and 1 CFR part 51. You may obtain a copy from the Office of Food Additive Safety, 5100 Paint Branch Pkwy., College Park, MD 20740 or you may examine a copy at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 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.

(2) Acid value, not greater than 2, and hydroxyl value, not greater than 56 as determined by the methods entitled “Acid Value,” p. 934 and “Hydroxyl Value,” p. 936, respectively, in the Food Chemicals Codex, 5th ed., effective January 1, 2004, and incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academies Press, 500 Fifth St. NW., Washington, DC 20055 (Internet address http://www.nap.edu), or 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.

(3) Lead, not greater than 0.1 mg/kg as determined by the American Oil Chemists’ Society (A.O.C.S.) method Ca 18c–91, “Determination of Lead by Direct Graphite Furnace Atomic Absorption Spectrophotometry,” updated 1995, and incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from American Oil Chemists’ Society, P. O. Box 3489, Champaign, IL 61826-3489, or may be examined in the library at the Center for Food Safety and Applied Nutrition, 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.

(4) 1,4-Dioxane, not greater than 10 milligrams per kilogram (mg/kg), and ethylene oxide, not greater than 1 mg/kg, as determined by a gas chromatographic method entitled “Determination of Ethylene Oxide and 1,4-Dioxane by Headspace Gas Chromatography,” approved November 5, 1998, printed by Gattefosse S.A.S., and incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51; see paragraph (b)(1) of this section for availability of the incorporation by reference.

(c) The additive is used or intended for use as an excipient in dietary supplement tablets, capsules, and liquid formulations that are intended for ingestion in daily quantities measured in drops or similar small units of measure.

[71 FR 12620, Mar. 13, 2006]

§ 172.755 Stearyl monoglyceridyl citrate.

The food additive stearyl monoglyceridyl citrate may be safely used in food in accordance with the following provisions:

(a) The additive is prepared by controlled chemical reaction of the following:

<table>
<thead>
<tr>
<th>Reactant</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citric acid</td>
<td>Prepared by the glycerolysis of edible fats and oils or derived from fatty acids conforming with §172.860.</td>
</tr>
<tr>
<td>Monoglycerides of fatty acids.</td>
<td>Derived from fatty acids conforming with §172.860, or derived synthetically in conformity with §172.864.</td>
</tr>
<tr>
<td>Stearyl alcohol</td>
<td></td>
</tr>
</tbody>
</table>

(b) The additive stearyl monoglyceridyl citrate, produced as described under paragraph (a) of this section, meets the following specifications:

- Acid number 40 to 62.
- Total citric acid 15 to 18 percent.
- Saponification number 215–235.

(c) The additive is used or intended for use as an emulsion stabilizer in or with shortenings containing emulsifiers.
§ 172.765 Succistearin (stearoyl propylene glycol hydrogen succinate).

The food additive succistearin (stearoyl propylene glycol hydrogen succinate) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is the reaction product of succinic anhydride, fully hydrogenated vegetable oil (predominantly C₁₆ or C₁₈ fatty acid chain length), and propylene glycol.

(b) The additive meets the following specifications:
   - Acid number 50–150.
   - Hydroxyl number 15–50.
   - Succinated ester content 45–75 percent.

(c) The additive is used or intended for use as an emulsifier in or with shortenings and edible oils intended for use in cakes, cake mixes, fillings, icings, pastries, and toppings, in accordance with good manufacturing practice.

§ 172.770 Ethylene oxide polymer.

The polymer of ethylene oxide may be safely used as a foam stabilizer in fermented malt beverages in accordance with the following conditions:

(a) It is the polymer of ethylene oxide having a minimum viscosity of 1,500 centipoises in a 1 percent aqueous solution at 25 °C.

(b) It is used at a level not to exceed 300 parts per million by weight of the fermented malt beverage.

(c) The label of the additive bears directions for use to insure compliance with paragraph (b) of this section.

§ 172.775 Methacrylic acid-divinylbenzene copolymer.

Methacrylic acid-divinylbenzene copolymer may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is produced by the polymerization of methacrylic acid and divinylbenzene. The divinylbenzene functions as a cross-linking agent and constitutes a minimum of 4 percent of the polymer.

(b) Aqueous extractives from the additive do not exceed 2 percent (dry basis) after 24 hours at 25 °C.

(c) The additive is used as a carrier of vitamin B₁₂ in foods for special dietary use.

§ 172.780 Acacia (gum arabic).

The food additive may be safely used in food in accordance with the following prescribed conditions:

(a) Acacia (gum arabic) is the dried gummy exudate from stems and branches of trees of various species of the genus *Acacia*, family Leguminosae.

(b) The ingredient meets the specifications of the “Food Chemicals Codex,” 5th Ed. (2004), pp. 210 and 211, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the National Academies Press, 500 Fifth St. NW., Washington, DC 20001 (Internet address: http://www.nap.edu). Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 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.

(c) The ingredient is used as a thickener, emulsifier, or stabilizer in alcoholic beverages at a use level not to exceed 20 percent in the final beverage.

(70 FR 8304, Feb. 17, 2005)


The food additive may be safely used as an antimicrobial agent specific for *Listeria monocytogenes* (*L. monocytogenes*) in accordance with the following conditions:

(a) Identity. (1) The additive consists of a mixture of equal proportions of six different individually purified lytic-type (lacking lysogenic activity) bacteriophages (phages) specific against *L. monocytogenes*.

(2) Each phage is deposited at, and assigned an identifying code by, a scientifically-recognized culture collection, and is made available to FDA upon request.
(3) The additive is produced from one or more cell cultures of *L. monocytogenes* in a safe and suitable nutrient medium.

(b) Specifications. (1) The additive achieves a positive lytic result (OD<sub>600</sub> ≤ 0.06) when tested against any of the following *L. monocytogenes* isolates available from American Type Culture Collection (ATCC): ATCC 35152 (serogroup 1/2a), ATCC 19118 (serogroup 4b), and ATCC 15313 (serogroup 1/2b). The analytical method for determining the potency of the additive entitled “Determination of Potency of LMP–102TM,” dated October 9, 2003, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

(2) The mean phage titer of each monophage in the additive is 1 × 10<sup>9</sup> plaque forming units (PFU)/ml. The analytical method for determining phage titer entitled “Method to Determine Lytic Activity/Phage Titer,” dated November 6, 2001, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

(3) The phages present in the preparation must not contain a functional portion of any of the toxin-encoding sequences described in 40 CFR 725.421(d). No sequences derived from genes encoding bacterial 16S ribosomal RNA are present in the complete genomic sequence of the phages.

(4) *L. monocytogenes* toxin, listeriolysin O (LLO), is not greater than 5 hemolytic units (HU)/ml. The analytical method for determining LLO entitled “Quantitation of Listeriolysin O Levels in LMP–102TM,” dated September 27, 2004, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.


(6) The additive is negative for gram-positive and gram-negative bacteria capable of growing in commonly used microbiological media (e.g., Luria-Bertani (LB) medium), including *Escherichia coli*, *Salmonella* species and coagulase-positive *Staphylococci*, as determined by the “Method to Determine Microbial Contamination,” dated July 11, 2003, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

(7) Total organic carbon (TOC) is less than or equal to 36 mg/kg. The analytical method for determining TOC entitled “Determination of Total Organic Carbon by Automated Analyzer,” dated March 30, 2001, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

(c) Conditions of use. The additive is used in accordance with current good manufacturing practice to control *L. monocytogenes* by direct application to meat and poultry products that comply with the ready-to-eat definition in 9 CFR 430.1. Current good manufacturing practice is consistent with direct spray application of the additive at a rate of approximately 1 mL of the additive per 500 cm<sup>2</sup> product surface area.

[71 FR 47731, Aug. 18, 2006]
§ 172.800 Acesulfame potassium.

Acesulfame potassium (CAS Reg. No. 55589–62–3), also known as acesulfame K, may be safely used as a general-purpose sweetener and flavor enhancer in foods generally, except in meat and poultry, in accordance with current good manufacturing practice and in an amount not to exceed that reasonably required to accomplish the intended technical effect in foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use, under the following conditions:

(a) Acesulfame potassium is the potassium salt of 6-methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide.

(b) The additive meets the following specifications:

(1) Purity is not less than 99 percent on a dry basis. The purity shall be determined by a method titled “Acesulfame Potassium Assay,” 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, 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.

(2) Fluoride content is not more than 30 parts per million, as determined by method III of the Fluoride Limit Test of the Food Chemicals Codex, 3d Ed. (1981), p. 511, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, 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.

(c) If the food containing the additive is represented to be for special dietary uses, it shall be labeled in compliance with part 105 of this chapter.


§ 172.802 Acetone peroxides.

The food additive acetone peroxides may be safely used in flour, and in bread and rolls where standards of identity do not preclude its use, in accordance with the following prescribed conditions:

(a) The additive is a mixture of monomeric and linear dimeric acetone peroxide, with minor proportions of higher polymers, manufactured by reaction of hydrogen peroxide and acetone.

(b) The additive may be mixed with an edible carrier to give a concentration of: (1) 3 grams to 10 grams of hydrogen peroxide equivalent per 100 grams of the additive, plus carrier, for use in flour maturing and bleaching; or (2) approximately 0.75 gram of hydrogen peroxide equivalent per 100 grams of the additive, plus carrier, for use in dough conditioning.

(c) It is used or intended for use: (1) In maturing and bleaching of flour in a quantity not more than sufficient for such effect; and (2) as a dough-conditioning agent in bread and roll production at not to exceed the quantity of hydrogen peroxide equivalent necessary for the artificial maturing effect.

(d) To insure safe use of the additive, the label of the food additive container and any intermediate premix thereof shall bear, in addition to the other information required by the act:

(1) The name of the additive, “acetone peroxides.”

(2) The concentration of the additive expressed in hydrogen peroxide equivalents per 100 grams.

(3) Adequate use directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

§ 172.804 Aspartame.

The food additive aspartame may be safely used in food in accordance with good manufacturing practice as a sweetening agent and a flavor enhancer...
in foods for which standards of identity established under section 401 of the act do not preclude such use under the following conditions:

(a) Aspartame is the chemical 1-methyl N-L-α-aspartyl-L-phenylalanine (C14H18N2O5).

(b) The additive meets the specifications of the “Food Chemicals Codex,” 3d Ed. (1981) pp. 28–29 and First Supplement p. 5, which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food And Drug Administration, 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.

(c)(1) When aspartame is used as a sugar substitute tablet for sweetening hot beverages, including coffee and tea, L-leucine may be used as a lubricant in the manufacture of such tablets at a level not to exceed 3.5 percent of the weight of the tablet.

(2) When aspartame is used in baked goods and baking mixes, the amount of the additive is not to exceed 0.5 percent by weight of ready-to-bake products or of finished formulations prior to baking. Generally recognized as safe (GRAS) ingredients or food additives approved for use in baked goods shall be used in combination with aspartame to ensure its functionality as a sweetener in the final baked product. The level of aspartame used in these products is determined by an analytical method entitled “Analytical Method for the Determination of Aspartame and Diketopiperazine in Baked Goods and Baking Mixes,” October 6, 1992, which was developed by the Nutrasweet Co.Copies are available from the Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, or are available for inspection at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and 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.

(d) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The principal display panel of any intermediate mix of the additive for manufacturing purposes shall bear a statement of the concentration of the additive contained therein;

(2) The label of any food containing the additive shall bear, either on the principal display panel or on the information panel, the following statement:

PHENYLKETONURICS: CONTAINS PHENYLALANINE

The statement shall appear in the labeling prominently and conspicuously as compared to other words, statements, designs or devices and in bold type and on clear contrasting background in order to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(3) When the additive is used in a sugar substitute for table use, its label shall bear instructions not to use in cooking or baking.

(4) Packages of the dry, free-flowing additive shall prominently display the sweetening equivalence in teaspoons of sugar.

(e) If the food containing the additive purports to be or is represented for special dietary uses, it shall be labeled in compliance with part 105 of this chapter.

[39 FR 27319, July 26, 1974]

EDITORIAL NOTE: For Federal Register citations affecting §172.804, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.
§ 172.806 Azodicarbonamide.

The food additive azodicarbonamide may be safely used in food in accordance with the following prescribed conditions:

(a) It is used or intended for use:
   (1) As an aging and bleaching ingredient in cereal flour in an amount not to exceed 2.05 grams per 100 pounds of flour (0.0045 percent; 45 parts per million).
   (2) As a dough conditioner in bread baking in a total amount not to exceed 0.0045 percent (45 parts per million) by weight of the flour used, including any quantity of azodicarbonamide added to flour in accordance with paragraph (a)(1) of this section.

(b) To assure safe use of the additive:
   (1) The label and labeling of the additive and any intermediate premix prepared therefrom shall bear, in addition to the other information required by the Act, the following:
      (i) The name of the additive.
      (ii) A statement of the concentration or the strength of the additive in any intermediate premixes.
   (2) The label or labeling of the food additive shall also bear adequate directions for use.

§ 172.808 Copolymer condensates of ethylene oxide and propylene oxide.

Copolymer condensates of ethylene oxide and propylene oxide may be safely used in food under the following prescribed conditions:

(a) The additive consists of one of the following:
   (1) $\alpha$-Hydro-omega-hydroxy-poly(oxyethylene)poly(oxypropylene) (55–61 moles)poly(oxyethylene) block copolymer, having a molecular weight range of 9,760–13,200 and a cloud point above 100 °C in 1 percent aqueous solution.
   (2) $\alpha$-Hydro-omega-hydroxy-poly(oxyethylene)poly(oxypropylene) (53–59 moles)poly(oxyethylene) (14–16 moles) block copolymer, having a molecular weight range of 3,500–4,125 and a cloud point of 9 °C–12 °C in 10 percent aqueous solution.
   (3) $\alpha$-Hydro-omega-hydroxy-poly(oxyethylene)poly(oxypropylene) (minimum 15 moles)poly(oxyethylene) block copolymer, having a minimum average molecular weight of 1900 and a minimum cloud point of 9 °C–12 °C in 10 percent aqueous solution.
   (4) $\alpha$-Hydro-omega-hydroxy-poly(oxyethylene)poly(oxypropylene) (51–57 moles)poly(oxyethylene) block copolymer, having an average molecular weight of 14,000 and a cloud point above 100 °C in 1 percent aqueous solution.

(b) The additive is used or intended for use as follows:
   (1) The additive identified in paragraph (a)(1) of this section is used in practice as a solubilizing and stabilizing agent in flavor concentrates (containing authorized flavoring oils) for use in foods for which standards of identity established under section 401 of the Act do not preclude such use, provided that the weight of the additive does not exceed the weight of the flavoring oils in the flavor concentrate.
   (2) The additive identified in paragraph (a)(2) of this section is used as a processing aid and wetting agent in combination with dioctyl sodium sulfosuccinate for fumaric acid as prescribed in §172.810.
   (3) The additive identified in paragraph (a)(3) of this section is used:
      (i) As a surfactant and defoaming agent, at levels not to exceed 0.05 percent by weight, in scald baths for poultry defeathering, followed by potable water rinse. The temperatures of the scald baths shall be not less than 125 °F.
      (ii) As a foam control and rinse adjuvant in hog dehairing machines at a use level of not more than 5 grams per hog.

(4) The additive identified in paragraph (a)(4) of this section is used as a dough conditioner in yeast-leavened bakery products for which standards of identity established under section 401 of the Act do not preclude such use, provided that the amount of the additive dose not exceed 0.5 percent by weight of the flour used.


§ 172.809 Curdlan.

Curdlan may be safely used in accordance with the following conditions:

(a) Curdlan is a high molecular weight polymer of glucose (β-1,3-glucan; CAS Reg. No. 54724-00-4), produced by pure culture fermentation

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from the nonpathogenic and nontoxicogenic bacterium *Alcaligenes faecalis* var. *myxogenes*.

(b) Curdlan meets the following specifications when it is tested according to the methods described or referenced in the document entitled "Analytical Methods for Specification Tests for Curdlan," by Takeda Chemical Industries, Ltd., 12–10 Nihonbashı, 2-Chome, Chuo-ku, Tokyo, 103, Japan, 1996, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 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.

1. Positive for curdlan.
2. Assay for curdlan (calculated as anhydrous glucose), not less than 80 percent.
3. pH of 1 percent aqueous suspension, 6.0–7.5.
4. Lead, not more than 0.5 mg/kg.
5. Heavy metals (as Pb), not more than 0.002 percent.
6. Total nitrogen, not more than 0.2 percent.
7. Loss on drying, not more than 10 percent.
8. Residue on ignition, not more than 6 percent.
9. Gel strength of 2 percent aqueous suspension, not less than $600 \times 10^3$ dyne per square centimeter.
10. Aerobic plate count, not more than $10^8$ per gram.
11. Coliform bacteria, not more than 3 per gram.

(c) Curdlan is used or intended for use in accordance with good manufacturing practice as a formulation aid, processing aid, stabilizer and thickener, and texturizer in foods for which standards of identity established under section 401 of the act do not preclude such use.

§ 172.810 Dioctyl sodium sulfosuccinate.

The food additive dioctyl sodium sulfosuccinate, which meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 102–104, which is incorporated by reference (Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–744–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.), may be safely used in food in accordance with the following prescribed conditions:

(a) As a wetting agent in the following fumaric acid-acidulated foods: Dry gelatin dessert, dry beverage base, and fruit juice drinks, when standards of identity do not preclude such use. The labeling of the dry gelatin dessert and dry beverage base shall bear adequate directions for use, and the additive shall be used in such an amount that the finished gelatin dessert will contain not in excess of 15 parts per million of the additive and the finished beverage or fruit juice drink will contain not in excess of 10 parts per million of the additive.

(b) As a processing aid in sugar factories in the production of unrefined cane sugar, in an amount not in excess of 0.5 part per million of the additive per percentage point of sucrose in the juice, syrup, or massecuite being processed, and so used that the final molasses will contain no more than 25 parts per million of the additive.

(c) As a solubilizing agent on gums and hydrophilic colloids to be used in food as stabilizing and thickening agents, when standards of identity do not preclude such use. The additive is used in an amount not to exceed 0.5 percent by weight of the gums or hydrophilic colloids.

(d) As an emulsifying agent for cocoa fat in noncarbonated beverages containing cocoa, whereby the amount of
(e) As a dispersing agent in "cocoa with diocyl sodium sulfo succinate for manufacturing" that conforms to the provisions of §183.117 of this chapter and the use limitations prescribed in §172.520, in an amount not to exceed 0.4 percent by weight thereof.

(f) As a processing aid and wetting agent in combination with α-hydroxy-ω-hydroxy-poly(oxyethylene)-poly(oxypropylene) (53–59 moles) poly(oxyethylene) (14–16 moles) block copolymer, having a molecular weight range of 3,500–4,125 and a cloud point of 9 °C–12 °C in 10 percent aqueous solution, for fumaric acid used in fumaric acid-acidulated dry beverage base and in fumaric acid-acidulated fruit juice drinks, when standards of identity do not preclude such use. The labeling of the dry beverage base shall bear adequate directions for use, and the additives shall be used in such an amount that the finished beverage or fruit juice drink will contain not in excess of a total of 10 parts per million of the diocyl sodium sulfo succinate-block copolymer combination.

(d) To assure safe use of the additive:

(1) In addition to the other information required by the act, the label or labeling of the additive shall bear the name of the additive.

(2) The label of the additive shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

§172.812 Glycine.

The food additive glycine may be safely used for technological purposes in food in accordance with the following prescribed conditions:

(a) The additive complies with the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 140, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, 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.

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

<table>
<thead>
<tr>
<th>Uses</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not to exceed 1 percent of the combined weight of the formulation.</td>
<td></td>
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<tr>
<td>Not to exceed 0.5 percent.</td>
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<tr>
<td>Not to exceed 3.0 percent of the combined weight of the formulation.</td>
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</tr>
<tr>
<td>Not to exceed 1.0 percent of the combined weight of the formulation.</td>
<td></td>
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<tr>
<td>Not to exceed 0.5 percent by weight of the processed fat or oil.</td>
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</tbody>
</table>
§ 172.818

Methyl glucoside-coconut oil ester.

Methyl glucoside-coconut oil ester may be safely used in food in accordance with the following conditions:

(a) It is the methyl glucoside-coconut oil ester having the following specifications:

- Acid number: 10–20
- Hydroxyl number: 200–300
- pH (5% aqueous): 4.8–5.0
- Saponification number: 178–190

(b) It is used or intended for use as follows:

- As an aid in crystallization of sucrose and dextrose at a level not to exceed the minimum quantity required to produce its intended effect.
- As a surfactant in molasses at a level not to exceed 320 parts per million in the molasses.

§ 172.818 Oxystearin.

The food additive oxystearin may be safely used in foods, when such use is not precluded by standards of identity in accordance with the following conditions:

(a) The additive is a mixture of the glycerides of partially oxidized stearic and other fatty acids obtained by heating hydrogenated cottonseed or soybean oil under controlled conditions, in the presence of air and a suitable catalyst which is not a food additive as so defined. The resultant product meets the following specifications:

- Acid number: Maximum 15.
- Iodine number: Maximum 15.
- Saponification number: 225–240.
- Hydroxyl number: 30–45.
- Unsatifiable material: Maximum 0.8 percent.
- Refractive index (butyro): 60±1 at 48 °C.

(b) It is used or intended for use as a crystallization inhibitor in vegetable oils and as a release agent in vegetable oils and vegetable shortenings, whereby the additive does not exceed 0.125 percent of the combined weight of the oil or shortening.

(c) To assure safe use of the additive, the label and labeling of the additive container shall bear, in addition to the other information required by the Act:

- The name of the additive, "oxystearin".
- Adequate directions to provide an oil or shortening that complies with...
§ 172.820 Polyethylene glycol (mean molecular weight 200–9,500).

Polyethylene glycol identified in this section may be safely used in food in accordance with the following prescribed conditions:

(a) Identity. (1) The additive is an addition polymer of ethylene oxide and water with a mean molecular weight of 200 to 9,500.

(2) It contains no more than 0.2 percent total by weight of ethylene and diethylene glycols when tested by the analytical methods prescribed in paragraph (b) of this section.

(b) Analytical method. (1) The analytical method prescribed in the National Formulary XV (1980), page 1244, for polyethylene glycol 400 shall be used to determine the total ethylene and diethylene glycol content of polyethylene glycols having mean molecular weights of 450 or higher.

(2) The following analytical method shall be used to determine the total ethylene and diethylene glycol content of polyethylene glycols having mean molecular weights below 450.

**ANALYTICAL METHOD**

**ETHYLENE GLYCOL AND DIETHYLENE GLYCOL CONTENT OF POLYETHYLENE GLYCOLS**

The analytical method for determining ethylene glycol and diethylene glycol is as follows:

**APPARATUS**

Gas chromatograph with hydrogen flame ionization detector (Varian Aerograph 600 D or equivalent). The following conditions shall be employed with the Varian Aerograph 600 D gas chromatograph:

- Column temperature: 165 °C.
- Inlet temperature: 260 °C.
- Carrier gas (nitrogen) flow rate: 70 milliliters per minute.
- Hydrogen and air flow to burner: Optimize to give maximum sensitivity.
- Sample size: 2 microliters.
- Elution time: Ethylene glycol: 2.6 minutes. Diethylene glycol: 6.5 minutes.
- Recorder: –0.5 to +1.05 millivolt, full span, 1 second full response time.
- Syringe: 10-microliter (Hamilton 710 N or equivalent).
- Chromatograph column: 5 feet × ¼ inch, I.D. stainless steel tube packed with sorbitol (Mathieson-Coleman-Bell 2768 Sorbitol SX850, or equivalent) 12 percent in H₂O by weight on 60–80 mesh nonacid washed diatomaceous earth (Chromosorb W. Johns-Manville, or equivalent).

**REAGENTS AND MATERIALS**

- Carrier gas, nitrogen: Commercial grade in cylinder equipped with reducing regulator to provide 50 p.s.i.g. to the gas chromatograph.
- Ethylene glycol: Commercial grade. Purity if necessary, by distillation.
- Diethylene glycol: Commercial grade. Purity, if necessary, by distillation.
- Glycol standards: Prepare chromatographic standards by dissolving known amounts of ethylene glycol and diethylene glycol in water. Suitable concentrations for standardization range from 1 to 6 milligrams of each component per milliliter (for example 10 milligrams diluted to volume in a 10-milliliter volumetric flask is equivalent to 1 milligram per milliliter).

**STANDARDIZATION**

Inject a 2-microliter aliquot of the glycol standard into the gas chromatograph employing the conditions described above. Measure the net peak heights for the ethylene glycol and for the diethylene glycol. Record the values as follows:

- A = Peak height in millimeters of the ethylene glycol peak.
- B = Milligrams of ethylene glycol per milliliter of standard solution.
- C = Peak height in millimeters of the diethylene glycol peak.
- D = Milligrams of diethylene glycol per milliliter of standard solution.

**PROCEDURE**

Weigh approximately 4 grams of polyethylene glycol sample accurately into a 10-milliliter volumetric flask. Dilute to volume with water. Mix the solution thoroughly and inject a 2-microliter aliquot into the gas chromatograph. Measure the heights, in millimeters, of the ethylene glycol peak and of the diethylene glycol peak and record as E and F, respectively.

Percent ethylene glycol = \( \frac{E \times B}{A \times \text{sample weight in grams}} \)

Percent diethylene glycol = \( \frac{F \times D}{C \times \text{sample weight in grams}} \)

(c) Uses. It may be used, except in milk or preparations intended for addition to milk, as follows:

(1) As a coating, binder, plasticizing agent, and/or lubricant in tablets used for food.

(2) As an adjuvant to improve flavor and as a bodying agent in nonnutritive sweeteners identified in §180.37 of this chapter.
(3) As an adjuvant in dispersing vitamin and/or mineral preparations.

(4) As a coating on sodium nitrite to inhibit hygroscopic properties.

(d) Limitations. (1) It is used in an amount not greater than that required to produce the intended physical or technical effect.

(2) A tolerance of zero is established for residues of polyethylene glycol in milk.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.822 Sodium lauryl sulfate.

The food additive sodium lauryl sulfate may be safely used in food in accordance with the following conditions:

(a) The additive meets the following specifications:

(1) It is a mixture of sodium alkyl sulfates consisting chiefly of sodium lauryl sulfate \( \text{CH}_2(\text{CH}_2)_n\text{CH}_3\text{OSO}_2\text{Na} \).

(2) It has a minimum content of 90 percent sodium alkyl sulfates.

(b) It is used or intended for use:

(1) As an emulsifier in or with egg whites whereby the additive does not exceed the following limits:

Egg white solids, 1,000 parts per million.

Frozen egg whites, 125 parts per million.

Liquid egg whites, 125 parts per million.

(2) As a whipping agent at a level not to exceed 0.5 percent by weight of gelatine used in the preparation of marshmallows.

(3) As a surfactant in:

(i) Fumaric acid-acidulated dry beverage base whereby the additive does not exceed 25 parts per million of the finished beverage and such beverage base is not for use in a food for which a standard of identity established under section 401 of the Act precludes such use.

(ii) Fumaric acid-acidulated fruit juice drinks whereby the additive does not exceed 25 parts per million of the finished fruit juice drink and it is not used in a fruit juice drink for which a standard of identity established under section 401 of the Act precludes such use.

(4) As a wetting agent at a level not to exceed 10 parts per million in the partition of high and low melting fractions of crude vegetable oils and animal fats, provided that the partition step is followed by a conventional refining process that includes alkali neutralization and deodorization of the fats and oils.

(c) To insure the safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the Act:

(1) The name of the additive, sodium lauryl sulfate.

(2) Adequate use directions to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.


§ 172.824 Sodium mono- and dimethyl naphthalene sulfonates.

The food additive sodium mono- and dimethyl naphthalene sulfonates may be safely used in accordance with the following prescribed conditions:

(a) The additive has a molecular weight range of 245–260.

(b) The additive is used or intended for use:

(1) In the crystallization of sodium carbonate in an amount not to exceed 250 parts per million of the sodium carbonate. Such sodium carbonate is used or intended for use in potable water systems to reduce hardness and aid in sedimentation and coagulation by raising the pH for the efficient utilization of other coagulation materials.

(2) As an anticaking agent in sodium nitrite at a level not in excess of 0.1 percent by weight thereof for authorized uses in cured fish and meat.

(c) In addition to the general labeling requirements of the Act:

(1) Sodium carbonate produced in accordance with paragraph (b)(1) of this section shall be labeled to show the presence of the additive and its label or labeling shall bear adequate directions for use.

(2) Sodium nitrite produced in accordance with paragraph (b)(2) of this section shall bear the labeling required by §172.175 and a statement declaring the presence of sodium mono- and dimethyl naphthalene sulfonates.

[42 FR 14491, Mar. 15, 1977, as amended at 63 FR 7069, Feb. 12, 1998]
§ 172.826 Sodium stearyl fumarate.

Sodium stearyl fumarate may be safely used in food in accordance with the following conditions:

(a) It contains not less than 99 percent sodium stearyl fumarate calculated on the anhydrous basis, and not more than 0.25 percent sodium stearyl maleate.

(b) The additive is used or intended for use:

(1) As a dough conditioner in yeast-leavened bakery products in an amount not to exceed 0.5 percent by weight of the flour used.

(2) As a conditioning agent in dehydrated potatoes in an amount not to exceed 1 percent by weight thereof.

(3) As a stabilizing agent in nonyeast-leavened bakery products in an amount not to exceed 1 percent by weight of the flour used.

(4) As a conditioning agent in processed cereals for cooking in an amount not to exceed 1 percent by weight of the dry cereal, except for foods for which standards of identity preclude such use.

(5) As a conditioning agent in starch-thickened or flour-thickened foods in an amount not to exceed 0.2 percent by weight of the food.

§ 172.828 Acetylated monoglycerides.

The food additive acetylated monoglycerides may be safely used in or on food in accordance with the following prescribed conditions:

(a) The additive is manufactured by:

(1) The interesterification of edible fats with triacetin and in the presence of catalytic agents that are not food additives or are authorized by regulation, followed by a molecular distillation or by steam stripping; or

(2) The direct acetylation of edible monoglycerides with acetic anhydride without the use of catalyst or molecular distillation, and with the removal by vacuum distillation, if necessary, of the acetic acid, acetic anhydride, and triacetin.

(b) The food additive has a Reichert-Meissl value of 75–200 and an acid value of less than 6.

(c) The food additive is used at a level not in excess of the amount reasonably required to produce its intended effect in food, or in food-processing, food-packing, or food-storage equipment.

§ 172.829 Neotame.

(a) Neotame is the chemical \(N-(3,3\text{-dimethylbutyl})-L-\alpha\text{-aspartyl}-L\text{-phenylalanine}-1\text{-methyl ester} \) (CAS Reg. No. 165450–17–9).

(b) Neotame meets the following specifications when it is tested according to the methods described or referenced in the document entitled “Specifications and Analytical Methods for Neotame” dated April 3, 2001, by the NutraSweet Co., 699 North Wheeling Rd., Mount Prospect, IL 60056. The Director of the Office of the Federal Register has approved the incorporation by reference of this material in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740. Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch Pkwy., rm. 1C–100, 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.

(1) Assay for neotame, not less than 97.0 percent and not more than 102.0 percent on a dry basis.

(2) Free dipeptide acid \(N-(3,3\text{-dimethylbutyl})-L-\alpha\text{-aspartyl}-L\text{-phenylalanine}\), not more than 1.5 percent.

(3) Other related substances, not more than 2.0 percent.

(4) Lead, not more than 2.0 milligrams per kilogram.

(5) Water, not more than 5.0 percent.

(6) Residue on ignition, not more than 0.2 percent.

(7) Specific rotation, determined at 20 °C \([\alpha]_D\): –40.4° to 43.4° calculated on a dry basis.

(c) The food additive neotame may be safely used as a sweetening agent and
§ 172.832 Monoglyceride citrate.

A food additive that is a mixture of glyceryl monooleate and its citric acid monoester manufactured by the reaction of glyceryl monooleate with citric acid under controlled conditions may be safely used as a synergist and solubilizer for antioxidants in oils and fats, when used in accordance with the conditions prescribed in this section.

(a) The food additive meets the following specifications:

Acid number, 70–100.

Total citric acid (free and combined), 14 percent–17 percent.

(b) It is used, or intended for use, in antioxidant formulations for addition to oils and fats whereby the additive does not exceed 200 parts per million of the combined weight of the oil or fat and the additive.

(c) To assure safe use of the additive:
(1) The container label shall bear, in addition to the other information required by the Act, the name of the additive.

(2) The label or accompanying labeling shall bear adequate directions for the use of the additive which, if followed, will result in a food that complies with the requirements of this section.

§ 172.833 Sucrose acetate isobutyrate (SAIB).

Sucrose acetate isobutyrate may be safely used in foods in accordance with the following prescribed conditions:

(a) Sucrose acetate isobutyrate (CAS Reg. No. 27216–37–1), or SAIB, is the chemical \( \alpha \)-D-glucopyranoside, O-acetyl-tris-O-(2-methyl-1-oxopropyl)-\( \beta \)-D-fructofuranosyl, acetate tris(2-methyl propanoate).

(b) SAIB, a pale, straw-colored liquid, meets the following specifications: (1) Assay: Not less than 98.8 percent and not more than 101.9 percent, based on the following formula:

\[
\text{Assay} = \left( \frac{SV}{0.10586} \right) \div 56.1 \times 100
\]

Where \( SV = \) Saponification value


(4) Lead: Not to exceed 1.0 milligrams/kilogram determined by the "Atomic Absorption Spectrophotometric Graphite Furnace Method, Method I," in the "Food Chemicals Codex," 4th ed. (1996), pp. 763 and 764, with an attached modification to the sample digestion section in Appendix III.B (July 1996), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Box 285, Washington, DC 20055 (Internet http://www.nap.edu), or 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.

(5) Triacetin: Not to exceed 0.10 percent determined by gas chromatography as described in the "Guide to Specifications for General Notices, General Analytical Techniques, Identification Tests, Test Solutions, and Other Reference Materials," in the "Compendium of Food Additive Specifications, Addendum 4, FAO Food and Nutrition Paper 5, Revision 2," (1991), pp. 13–26, which is incorporated by reference; see paragraph (b)(2) of this section for availability of the incorporation by reference.

(c) The food additive is used as a stabilizer (as defined in §170.3(o)(28) of this chapter) of emulsions of flavoring oils in nonalcoholic beverages.

(d) The total SAIB content of a beverage containing the additive does not
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§ 172.834 Ethoxylated mono- and diglycerides.

The food additive ethoxylated mono- and diglycerides (polyoxyethylene (20) mono- and diglycerides of fatty acids) (polyglycerate 60) may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by:

(1) Glycerolysis of edible fats primarily composed of stearic, palmitic, and myristic acids; or

(2) Direct esterification of glycerol with a mixture of primarily stearic, palmitic, and myristic acids;

to yield a product with less than 0.3 acid number and less than 0.2 percent water, which is then reacted with ethylene oxide.

(b) The additive meets the following specifications:

- Saponification number, 65–75.
- Acid number, 0–2.
- Oxyethylene content, 60.5–65.0 percent.

(c) The additive is used or intended for use in the following foods when standards of identity established under section 401 of the Act do not preclude such use:

<table>
<thead>
<tr>
<th>Use</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. As an emulsifier in pan-release agents for and as a dough conditioner in yeast-leavened bakery products.</td>
<td>Not to exceed levels required to produce the intended effects, total not to exceed 0.5 percent by weight of the flour used.</td>
</tr>
<tr>
<td>2. As an emulsifier in cakes and cake mixes.</td>
<td>Not to exceed 0.5 percent by weight of the dry ingredients.</td>
</tr>
<tr>
<td>3. As an emulsifier in whipped vegetable oil toppings and topping mixes.</td>
<td>Not to exceed 0.45 percent by weight of the finished whipped vegetable oil toppings.</td>
</tr>
<tr>
<td>4. As an emulsifier in icings and icing mixes.</td>
<td>Not to exceed 0.5 percent by weight of the finished icings.</td>
</tr>
<tr>
<td>5. As an emulsifier in frozen desserts.</td>
<td>Not to exceed 0.2 percent by weight of the finished frozen desserts.</td>
</tr>
<tr>
<td>6. As an emulsifier in edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee.</td>
<td>Not to exceed 0.4 percent by weight of the finished edible vegetable fat-water emulsions.</td>
</tr>
</tbody>
</table>

(d) When the name “polyglycerate 60” is used in labeling it shall be followed by either “polyoxyethylene (20) mono-and diglycerides of fatty acids” or “ethoxylated mono- and diglycerides” in parentheses.

§ 172.836 Polysorbate 60.

The food additive polysorbate 60 (polyoxyethylene (20) sorbitan monostearate) which is a mixture of polyoxyethylene ethers of mixed partial stearic and palmitic acid esters of sorbitol anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield a product with a maximum acid number of 10 and a maximum water content of 0.2 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

- Saponification number 45–55.
- Acid number 0–2.
- Hydroxyl number 81–96.
- Oxyethylene content 65 percent–69.5 percent.

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

(1) As an emulsifier in whipped edible oil topping with or without one or a combination of the following:

- Sorbitan monostearate;
- Polysorbate 65;
- Polysorbate 80;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped edible oil topping; except that a combination of the additive with sorbitan monostearate may be used in excess of 0.4 percent, provided that the amount of the additive does not exceed 0.77 percent and the amount of sorbitan monostearate does not exceed 0.27 percent of the weight of the finished whipped edible oil topping.

(2) As an emulsifier in cakes and cake mixes, with or without one or a combination of the following:

- Polysorbate 65.

(ii) Sorbitan monostearate.
When used alone, the maximum amount of polysorbate 60 shall not exceed 0.46 percent of the cake or cake mix, on a dry-weight basis. When used with polysorbate 65 and/or sorbitan monostearate, it shall not exceed 0.46 percent, nor shall the polysorbate 65 exceed 0.32 percent or the sorbitan monostearate exceed 0.61 percent, and no combination of these emulsifiers shall exceed 0.66 percent of the cake or cake mix, all calculated on a dry-weight basis.

(3) As an emulsifier, alone or in combination with sorbitan monostearate, in nonstandardized confectionery coatings and standardized cacao products specified in §§163.123, 163.130, 163.135, 163.140, 163.145, and 163.150 of this chapter, as follows:
(i) It is used alone in an amount not to exceed 0.5 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.
(ii) It is used with sorbitan monostearate in any combination of up to 0.5 percent of polysorbate 60 and up to 1 percent of sorbitan monostearate: Provided, That the total combination does not exceed 1 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(4) [Reserved]

(5) As an emulsifier in cake icings and cake fillings, with or without one or a combination of the following:
(i) Polysorbate 65.
(ii) Sorbitan monostearate.
When used alone, the maximum amount of polysorbate 60 shall not exceed 0.46 percent of the weight of the cake icings and cake fillings. When used with polysorbate 65 and/or sorbitan monostearate, it shall not exceed 0.46 percent, nor shall the polysorbate 65 exceed 0.32 percent or the sorbitan monostearate exceed 0.7 percent, and no combination of these emulsifiers shall exceed 1 percent of the weight of the cake icing or cake filling.

(6) To impart greater opacity to sugar-type confection coatings whereby the maximum amount of the additive does not exceed 0.2 percent of the weight of the finished sugar coating.

(7) As an emulsifier in nonstandardized dressings whereby the maximum amount of the additive does not exceed 0.3 percent of the weight of the finished dressings.

(8) As an emulsifier, alone or in combination with polysorbate 80, in shortenings and edible oils intended for use in foods as follows, when standards of identity established under section 401 of the act do not preclude such use:
(i) It is used alone in an amount not to exceed 1 percent of the weight of the finished shortening or oil.
(ii) It is used with polysorbate 80 in any combination providing no more than 1 percent of polysorbate 60 and no more than 1 percent of polysorbate 80, provided that the total combination does not exceed 1 percent of the finished shortening or oil.
(iii) The 1-percent limitation specified in paragraph (c)(8) (i) and (ii) of this section may be exceeded in premix concentrates of shortening or edible oil if the labeling complies with the requirements of paragraph (d) of this section.

(9) As an emulsifier in solid-state, edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee, with or without one or a combination of the following:
(i) Polysorbate 65.
(ii) Sorbitan monostearate.
The maximum amount of the additive or additives shall not exceed 0.4 percent by weight of the finished edible vegetable fat-water emulsion.

(10) As a foaming agent in nonalcoholic mixes, to be added to alcoholic beverages in the preparation of mixed alcoholic drinks, at a level not to exceed 4.5 percent by weight of the nonalcoholic mix.

(11) As a dough conditioner in yeast-leavened bakery products in an amount not to exceed 0.5 percent by weight of the flour used.

(12) As an emulsifier, alone or in combination with sorbitan monostearate, in the minimum quantity required to accomplish the intended effect, in formulations of white mineral oil conforming with §172.878 and/or petroleum wax conforming with §172.886 for use as protective coatings on raw fruits and vegetables.
(13) As a dispersing agent in artificially sweetened gelatin desserts and in artificially sweetened gelatin dessert mixes, whereby the amount of the additive does not exceed 0.5 percent on a dry-weight basis.

(14) As an emulsifier in chocolate flavored syrups, whereby the maximum amount of the additive does not exceed 0.05 percent in the finished product.

(15) As a surfactant and wetting agent for natural and artificial colors in food as follows:
   (i) In powdered soft drink mixes in an amount not to exceed 4.5 percent by weight of the mix.
   (ii) In sugar-based gelatin dessert mixes in an amount not to exceed 0.5 percent by weight of the mix.
   (iii) In artificially sweetened gelatin dessert mixes in an amount not to exceed 3.6 percent by weight of the mix.
   (iv) In sugar-based pudding mixes in an amount not to exceed 0.5 percent by weight of the mix.
   (v) In artificially sweetened pudding mixes in an amount not to exceed 0.5 percent by weight of the mix.

(16) As an emulsifier in ice cream, frozen custard, fruit sherbet, and nonstandardized frozen desserts when used alone or in combination with polysorbate 65 and/or polysorbate 80, whereby the maximum amount of the additives, alone or in combination, does not exceed 0.1 percent of the finished frozen dessert.

(d) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate premixes shall bear:
   (i) The name of the additive.
   (ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

§ 172.838 Polysorbate 65.

The food additive polysorbate 65 (polyoxyethylene sorbitan tristearate), which is a mixture of polyoxyethylene ethers of mixed stearic acid esters of sorbitol anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield a product with a maximum acid number of 15 and a maximum water content of 0.2 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

- Saponification number 88–98.
- Acid number 0–2.
- Hydroxyl number 44–60.
- Oxyethylene content 46 percent–50 percent.

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

(1) As an emulsifier in ice cream, frozen custard, ice milk, fruit sherbet and nonstandardized frozen desserts when used alone or in combination with polysorbate 80, whereby the maximum amount of the additives, alone or in combination, does not exceed 0.1 percent of the finished frozen dessert.

(2) As an emulsifier in cakes and cake mixes, with or without one or a combination of the following:
   (i) Sorbitan monostearate.
   (ii) Polysorbate 60.

When used alone, the maximum amount of polysorbate 65 shall not exceed 0.32 percent of the cake or cake mix, on a dry-weight basis. When used with sorbitan monostearate and/or polysorbate 60, it shall not exceed 0.32 percent, nor shall the sorbitan monostearate exceed 0.61 percent or the polysorbate 60 exceed 0.46 percent, and no combination of these emulsifiers shall exceed 0.66 percent of the cake or cake mix, all calculated on a dry-weight basis.

(3) As an emulsifier in whipped edible oil topping with or without one or a combination of the following:
   (i) Sorbitan monostearate.
   (ii) Polysorbate 60.
   (iii) Polysorbate 80.

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped edible oil topping.

§ 172.840 Polysorbate 80.

The food additive polysorbate 80 (polyoxyethylene (20) sorbitan monooleate), which is a mixture of polyoxyethylene ethers of mixed partial oleic acid esters of sorbitan anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting oleic acid (usually containing associated fatty acids) with sorbitol to yield a product with a maximum acid number of 7.5 and a maximum water content of 0.5 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

- Saponification number 45–55.
- Acid number 0–2.
- Oxyethylene content 65 percent–69.5 percent.

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

(1) An emulsifier in ice cream, frozen custard, ice milk, fruit sherbet, and nonstandardized frozen desserts, when used alone or in combination with polysorbate 65 whereby the maximum amount of the additives, alone or in combination, does not exceed 0.1 percent of the finished frozen dessert.

(2) In yeast-defoamer formulations whereby the maximum amount of the additive does not exceed 4 percent of the finished yeast defoamer and the maximum amount of the additive in the yeast from such use does not exceed 4 parts per million.

(3) As a solubilizing and dispersing agent in pickles and pickle products, whereby the maximum amount of the additive does not exceed 500 parts per million.

(4) As a solubilizing and dispersing agent in:

- Vitamin-mineral preparations containing calcium caseinate in the absence of fat-soluble vitamins, whereby the maximum intake of polysorbate 80 shall not exceed 175 milligrams from the recommended daily dose of the preparations.
- Vitamin and vitamin-mineral preparations containing no calcium caseinate, whereby the maximum intake of polysorbate 80 shall not exceed 300 milligrams from the recommended daily dose of the preparations.
- Vitamin-mineral preparations containing both calcium caseinate and fat-soluble vitamins, whereby the maximum intake of polysorbate 80 shall not exceed 475 milligrams from the recommended daily dose of the preparations.

(5) As a surfactant in the production of coarse crystal sodium chloride whereby the maximum amount of the additive is not exceeded.
additive in the finished sodium chloride does not exceed 10 parts per million.

(6) In special dietary foods, as an emulsifier for edible fats and oils, with directions for use which provide for the ingestion of not more than 360 milligrams of polysorbate 80 per day.

(7) As a solubilizing and dispersing agent for dill oil in canned spiced green beans, not to exceed 30 parts per million.

(8) As an emulsifier, alone or in combination with polysorbate 60, in shortenings and edible oils intended for use in foods as follows, when standards of identity established under section 401 of the act do not preclude such use:

(i) It is used alone in an amount not to exceed 1 percent of the weight of the finished shortening or oil.

(ii) It is used with polysorbate 60 in any combination providing no more than 1 percent of polysorbate 80 and no more than 1 percent of polysorbate 60, provided that the total combination does not exceed 1 percent of the finished shortening or oil.

(iii) The 1-percent limitation specified in paragraph (c)(8)(i) and (ii) of this section may be exceeded in premix concentrates of shortening or edible oil if the labeling complies with the requirements of paragraph (d) of this section.

(9) As an emulsifier in whipped edible oil topping with or without one or a combination of the following:

(i) Sorbitan monostearate;
(ii) Polysorbate 60;
(iii) Polysorbate 65;
whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped edible oil topping.

(10) It is used as a wetting agent in scald water for poultry defeathering, followed by potable water rinse. The concentration of the additive in the scald water does not exceed 0.0175 percent.

(11) As a dispersing agent in gelatin desserts and in gelatin dessert mixes, whereby the amount of the additive does not exceed 0.082 percent on a dry-weight basis.

(12) As an adjuvant added to herbicide use and plant-growth regulator use dilutions by a grower or applicator prior to application of such dilutions to the growing crop. Residues resulting from such use are exempt from the requirement of a tolerance. When so used or intended for use, the additive shall be exempt from the requirements of paragraph (d)(1) of this section.

(13) As a defoaming agent in the preparation of the creaming mixture for cottage cheese and lowfat cottage cheese, as identified in §§133.128 and 133.131 of this chapter, respectively, whereby the amount of the additive does not exceed .008 percent by weight of the finished products.

(14) As a surfactant and wetting agent for natural and artificial colors for use in barbecue sauce where the level of the additive does not exceed 0.005 percent by weight of the barbecue sauce.

(d) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate premixes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

§ 172.841 Polydextrose.

Polydextrose as identified in this section may be safely used in food in accordance with the following prescribed conditions:

(a)(1) Polydextrose (CAS Reg. No. 68424–04–4) is a partially metabolizable water-soluble polymer prepared by the condensation of a melt which consists either of approximately 80 percent D-glucose, 10 percent sorbitol, and 1 percent citric acid or of approximately 90 percent D-glucose, 10 percent sorbitol, and 0.1 percent phosphoric acid, on a weight basis.

(2) Polydextrose may be partially neutralized with potassium hydroxide, or partially reduced by transition metal catalytic hydrogenation in aqueous solution.
§ 172.842 Sorbitan monostearate.

The food additive sorbitan monostearate, which is a mixture of partial stearic and palmitic acid esters of sorbitol anhydrides, may be safely used in or on food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield essentially a mixture of esters.

(b) The food additive meets the following specifications:

- Saponification number, 147–157
- Acid number, 5–10
- Hydroxyl number, 235–260

(c) It is used or intended for use, alone or in combination with polysorbate 60 as follows:

1. As an emulsifier in whipped edible oil topping with or without one or a combination of the following:
   - Polysorbate 60;
   - Polysorbate 65;
   - Polysorbate 80;
   - Provided, that the amount of the additive does not exceed 0.27 percent and the amount of polysorbate 60 does not exceed 0.77 percent of the weight of the finished whipped edible oil topping.

2. As an emulsifier in cakes and cake mixes, with or without one or a combination of the following:
   - Polysorbate 65.
   - Polysorbate 60.
   - When used alone, the maximum amount of sorbitan monostearate shall not exceed 0.61 percent of the cake or cake mix, on a dry-weight basis. When used with polysorbate 65 and/or polysorbate 60, it shall not exceed 0.61 percent, nor shall the polysorbate 65 exceed 0.32 percent or the polysorbate 60 exceed 0.46 percent, and no combination of the emulsifiers shall exceed 0.66 percent of the weight of the finished whipped edible oil topping.

3. As an emulsifier, alone or in combination with polysorbate 60 in non-standardized confectionery coatings and standardized cacao products specified in §§ 163.123, 163.130, 163.135, 163.140, 163.145, and 163.150 of this chapter, as follows:

- Provides, that the amount of the additive does not exceed 0.61 percent of the weight of the finished whipped edible oil topping.

(i) It is used alone in an amount not to exceed 1 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.
(ii) It is used with polysorbate 60 in any combination of up to 1 percent sorbitan monostearate and up to 0.5 percent polysorbate 60 provided that the total combination does not exceed 1 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(4) As an emulsifier in cake icings and cake fillings, with or without one or a combination of the following:
   (i) Polysorbate 65.
   (ii) Polysorbate 60.

When used alone, the maximum amount of sorbitan monostearate shall not exceed 0.7 percent of the weight of the cake icing or cake filling. When used with polysorbate 65 and/or polysorbate 60, it shall not exceed 0.7 percent, nor shall the polysorbate 65 exceed 0.52 percent or the polysorbate 60 exceed 0.46 percent, and no combination of these emulsifiers shall exceed 1 percent of the weight of the cake icing or cake filling.

(5) As an emulsifier in solid-state, edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee, with or without one or a combination of the following:
   (i) Polysorbate 60.
   (ii) Polysorbate 65.

The maximum amount of the additive or additives shall not exceed 0.4 percent by weight of the finished edible vegetable fat-water emulsion.

(6) It is used alone as a rehydration aid in the production of active dry yeast in an amount not to exceed 1 percent by weight of the dry yeast.

(7) As an emulsifier, alone or in combination with polysorbate 60, in the minimum quantity required to accomplish the intended effect, in formulations of white mineral oil conforming with §172.878 and/or petroleum wax conforming with §172.886 for use as protective coatings on raw fruits and vegetables.

(d) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate premixes shall bear:
   (i) The name of the additive.
   (ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.


§ 172.844 Calcium stearoyl-2-lactylate.
The food additive calcium stearoyl-2-lactylate may be safely used in or on food in accordance with the following prescribed conditions:

(a) The additive, which is a mixture of calcium salts of stearoyl lactylic acids and minor proportions of other calcium salts of related acids, is manufactured by the reaction of stearic acid and lactic acid and conversion to the calcium salts.

(b) The additive meets the following specifications:

   Acid number, 50-86.
   Calcium content, 4.2-5.2 percent.
   Lactic acid content, 32-38 percent.
   Ester number, 125-164.

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

   (1) As a dough conditioner in yeast-leavened bakery products and prepared mixes for yeast-leavened bakery products in an amount not to exceed 0.5 part for each 100 parts by weight of flour used.
   (2) As a whipping agent in:
      (i) Liquid and frozen egg white at a level not to exceed 0.05 percent.
      (ii) Dried egg white at a level not to exceed 0.5 percent.
      (iii) Whipped vegetable oil topping at a level not to exceed 0.3 percent of the weight of the finished whipped vegetable oil topping.
   (3) As a conditioning agent in dehydrated potatoes in an amount not to exceed 0.5 percent by weight thereof.

(d) To assure safe use of the additive:
   (1) The label and labeling of the food additive and any intermediate premix prepared therefrom shall bear, in addition to the other information required by the act, the following:
§ 172.846 Sodium stearoyl lactylate.

The food additive sodium stearoyl lactylate (CAS Reg. No. 25–383–997) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive, which is a mixture of sodium salts of stearoyl lactylic acids and minor proportions of sodium salts of related acids, is manufactured by the reaction of stearic acid and lactic acid and conversion to the sodium salts.

(b) The additive meets the specifications of the “Food Chemicals Codex,” 3d Ed. (1981), pp. 300–301, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, 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.

(c) It is used or intended for use as follows when standards of identity established under section 401 of the Act do not preclude such use:

(1) As a dough strengthener, emulsifier, or processing aid in baked products, pancakes, and waffles, in an amount not to exceed 0.5 part for each 100 parts by weight of flour used.

(2) As a surface-active agent, emulsifier, or stabilizer in icings, fillings, puddings, and toppings, at a level not to exceed 0.2 percent by weight of the finished food.

(3) As an emulsifier or stabilizer in liquid and solid edible fat-water emulsions intended for use as substitutes for milk or cream in beverages, coffee, at a level not to exceed 0.3 percent by weight of the finished edible fat-water emulsion.

(4) As a formulation aid, processing aid, or surface-active agent in dehydrated potatoes, in an amount not to exceed 0.5 percent of the dry weight of the food.

(5) As an emulsifier, stabilizer, or texturizer in snack dips, at a level not to exceed 0.2 percent by weight of the finished food.

(6) As an emulsifier, stabilizer, or texturizer in cheese substitutes and imitations and cheese product substitutes and imitations, at a level not to exceed 0.2 percent by weight of the finished food.

(7) As an emulsifier, stabilizer, or texturizer in sauces or gravies, and the products containing the same, in an amount not to exceed 0.25 percent by weight of the finished product.

(8) In prepared mixes for each of the foods listed in paragraphs (c) (1) through (7) of this section, provided the additive is used only as specified in each of those paragraphs.

(9) As an emulsifier, stabilizer, or texturizer in cream liqueur drinks, at a level not to exceed 0.5 percent by weight of the finished product.


§ 172.848 Lactylic esters of fatty acids.

Lactylic esters of fatty acids may be safely used in food in accordance with the following prescribed conditions:

(a) They are prepared from lactic acid and fatty acids meeting the requirements of §172.860(b) and/or oleic acid derived from tall oil fatty acids meeting the requirements of §172.862.

(b) They are used as emulsifiers, plasticizers, or surface-active agents in the following foods, when standards of identity do not preclude their use:

<table>
<thead>
<tr>
<th>Foods</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bakery mixes</td>
<td>As substitutes for milk or cream in beverage coffee.</td>
</tr>
<tr>
<td>Baked products</td>
<td>For household use.</td>
</tr>
<tr>
<td>Cake icings, fillings, and toppings</td>
<td></td>
</tr>
<tr>
<td>Dehydrated fruits and vegetables</td>
<td></td>
</tr>
<tr>
<td>Edible vegetable fat-water emulsions</td>
<td></td>
</tr>
<tr>
<td>Frozen desserts</td>
<td>As substitutes for milk or cream in beverage coffee.</td>
</tr>
<tr>
<td>Liquid shortening</td>
<td>For household use.</td>
</tr>
<tr>
<td>Pancake mixes</td>
<td></td>
</tr>
<tr>
<td>Precooked instant rice</td>
<td></td>
</tr>
</tbody>
</table>

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(c) They are used in an amount not greater than required to produce the intended physical or technical effect, and they may be used with shortening and edible fats and oils when such are required in the foods identified in paragraph (b) of this section.

§ 172.850 Lactylated fatty acid esters of glycerol and propylene glycol.

The food additive lactylated fatty acid esters of glycerol and propylene glycol may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a mixture of esters produced by the lactylation of a product obtained by reacting edible fats or oils with propylene glycol.

(b) The additive meets the following specifications: Water insoluble combined lactic acid, 14–18 percent; and acid number, 12 maximum.

(c) It is used in amounts not in excess of that reasonably required to produce the intended physical effect as an emulsifier, plasticizer, or surface-active agent in food.

§ 172.852 Glyceryl-lacto esters of fatty acids.

Glyceryl-lacto esters of fatty acids (the lactic acid esters of mono- and diglycerides) may be safely used in food in accordance with the following prescribed conditions:

(a) They are manufactured from glycerin, lactic acid, and fatty acids conforming with §172.860 and/or oleic acid derived from tall oil fatty acids conforming with §172.862 and/or edible fats and oils.

(b) They are used in amounts not in excess of those reasonably required to accomplish their intended physical or technical effect as emulsifiers and plasticizers in food.

§ 172.854 Polyglycerol esters of fatty acids.

Polyglycerol esters of fatty acids, up to and including the decaglycerol esters, may be safely used in food in accordance with the following prescribed conditions:

(a) They are prepared from corn oil, cottonseed oil, lard, palm oil from fruit, peanut oil, safflower oil, sesame oil, soybean oil, and tallow and the fatty acids derived from these substances (hydrogenated and nonhydrogenated) meeting the requirements of §172.860(b) and/or oleic acid derived from tall oil fatty acids meeting the requirements of §172.862.

(b) They are used as emulsifiers in food, in amounts not greater than that required to produce the intended physical or technical effect.

(c) Polyglycerol esters of a mixture of stearic, oleic, and coconut fatty acids are used as a cloud inhibitor in vegetable and salad oils when use is not precluded by standards of identity. The fatty acids used in the production of the polyglycerol esters meet the requirements of §172.860(b), and the polyglycerol esters are used at a level not in excess of the amount required to perform its cloud-inhibiting effect. Oleic acid derived from tall oil fatty acids conforming with §172.862 may be used as a substitute for or together with the oleic acid permitted by this paragraph.

(d) Polyglycerol esters of butter oil fatty acids are used as emulsifiers in combination with other approved emulsifiers in dry, whipped topping base. The fatty acids used in the production of the polyglycerol esters meet the requirements of §172.860(b), and the polyglycerol esters are used at a level not in excess of the amount required to perform their emulsifying effect.

§ 172.856 Propylene glycol mono- and diesters of fats and fatty acids.

Propylene glycol mono- and diesters of fats and fatty acids may be safely used in food, subject to the following prescribed conditions:

(a) They are produced from edible fats and/or fatty acids in compliance with §172.860 and/or oleic acid derived from tall oil fatty acids in compliance with §172.862.

(b) They are used in food in amounts not in excess of that reasonably required to produce their intended effect.

§ 172.858 Propylene glycol alginate.

The food additive propylene glycol alginate (CAS Reg. No. 9005–37–2) may
be used as an emulsifier, flavoring adjuvant, formulation aid, stabilizer, surfactant, or thickener in foods in accordance with the following prescribed conditions:

(a) The additive meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 256, which is incorporated by reference (Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, 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.), and the additional specification that it shall have up to 85 percent of the carboxylic acid groups esterified with the remaining groups either free or neutralized.

(b) The additive is used or intended for use in the following foods as defined in §170.3(n) of this chapter, when standards of identity established under section 401 of the act do not preclude such use:

(1) As a stabilizer in frozen dairy desserts, in fruit and water ices, and in confections and frostings at a level not to exceed 0.5 percent by weight of the finished product.

(2) As an emulsifier, flavoring adjuvant, stabilizer, or thickener in baked goods at a level not to exceed 0.5 percent by weight of the finished product.

(3) As an emulsifier, stabilizer, or thickener in cheeses at a level not to exceed 0.9 percent by weight of the finished product.

(4) As an emulsifier, stabilizer, or thickener in fats and oils at a level not to exceed 1.1 percent by weight of the finished product.

(5) As an emulsifier, stabilizer, or thickener in gelatins and puddings at a level not to exceed 0.6 percent by weight of the finished product.

(6) As a stabilizer or thickener in gravies and in sweet sauces at a level not to exceed 0.5 percent by weight of the finished product.

(7) As a stabilizer in jams and jellies at a level not to exceed 0.4 percent by weight of the finished product.

(8) As an emulsifier, stabilizer, or thickener in condiments and relishes at a level not to exceed 0.6 percent by weight of the finished product.

(9) As a flavoring adjunct or adjuvant in seasonings and flavors at a level not to exceed 1.7 percent by weight of the finished product.

(10) As an emulsifier, flavoring adjuvant, formulation aid, stabilizer or thickener, or surface active agent in other foods, where applicable, at a level not to exceed 0.3 percent by weight of the finished product.

(c) To ensure safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the act:

(1) The name of the additive, “propylene glycol alginate” or “propylene glycol ester of alginic acid”.

(2) Adequate directions for use.

[47 FR 29950, July 9, 1982]

§ 172.859 Sucrose fatty acid esters.

Sucrose fatty acid esters identified in this section may be safely used in accordance with the following prescribed conditions:

(a) Sucrose fatty acid esters are the mono-, di-, and tri-esters of sucrose with fatty acids and are derived from sucrose and edible tallow or hydrogenated edible tallow or edible vegetable oils. The only solvents which may be used in the preparation of sucrose fatty acid esters are those generally recognized as safe in food or regulated for such use by an appropriate section in this part. Ethyl acetate or methyl ethyl ketone or dimethyl sulfoxide and isobutyl alcohol (2-methyl-1-propanol) may be used in the preparation of sucrose fatty acid esters.

(b) Sucrose fatty acid esters meet the following specifications:

(1) The total content of mono-, di-, and tri-esters is not less than 80 percent as determined by a method title “Sucrose Fatty Acid Esters, Method of Assay,” 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, 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.
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ted “Determination of Dimethyl Sulf-oxide,” 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, 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.

(11) The total isobutyl alcohol (2-methyl-1-propanol) content is not more than 10 parts per million as determined by a method entitled “Determination of Isobutyl Alcohol,” 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, 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.

(c) Sucrose fatty acid esters may be used as follows when standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use:

(1) As emulsifiers as defined in §170.3(o)(8) of this chapter, or as stabilizers as defined in §170.3(o)(28) of this chapter, in baked goods and baking mixes as defined in §170.3(n)(1) of this chapter, in chewing gum as defined in §170.3(n)(6) of this chapter, in coffee and tea beverages with added dairy ingredients and/or dairy product analogues, in confections and frostings as defined in §170.3(n)(9) of this chapter, in dairy product analogues as defined in §170.3(n)(10) of this chapter, in frozen dairy desserts and mixes as defined in §170.3(n)(20) of this chapter, and in whipped milk products.

(2) As texturizers as defined in §170.3(o)(32) of this chapter in biscuit mixes, in chewing gum as defined in §170.3(n)(6) of this chapter, in confections and frostings as defined in
§ 172.860 Fatty acids.

The food additive fatty acids may be safely used in food and in the manufacture of food components in accordance with the following prescribed conditions:

(a) The food additive consists of one or any mixture of the following straight-chain monobasic carboxylic acids and their associated fatty acids manufactured from fats and oils derived from edible sources: Capric acid, caprylic acid, lauric acid, myristic acid, oleic acid, palmitic acid, and stearic acid.

(b) The food additive meets the following specifications:

(1) Unsaponifiable matter does not exceed 2 percent.

(2) It is free of chick-edema factor:

(i) As evidenced during the bioassay method for determining the chick-edema factor as prescribed in paragraph (c)(2) of this section; or

(ii) As evidenced by the absence of chromatographic peaks with a retention time relative to aldrin (RA) between 10 and 25, using the gas chromatographic-electron capture method prescribed in paragraph (c)(3) of this section. If chromatographic peaks are found with RA values between 10 and 25, the food additive shall meet the requirements of the bioassay method prescribed in paragraph (c)(2) of this section for determining chick-edema factor.

(c) For the purposes of this section:

(1) Unsaponifiable matter shall be determined by the method described in the 13th Ed. (1980) of the “Official Methods of Analysis of the Association of Official Analytical Chemists,” which is incorporated by reference. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, 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.

(2) Chick-edema factor shall be determined by the bioassay method described in “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th Ed. (1980), sections 28.127–28.130, 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.

(3) The gas chromatographic-electron capture method for testing fatty acids for chick-edema shall be the method described in the “Journal of the Association of Official Analytical Chemists,” Volume 50 (No. 1), pages 216–218 (1967), or the modified method using a sulfuric acid clean-up procedure, as described in the “Journal of the Association of the Official Analytical Chemists,” Volume 51 (No. 2), pages 489–490 (1968), which are incorporated by reference. See paragraph (c)(2) of this section for availability of these references.

(d) It is used or intended for use as follows:

(1) In foods as a lubricant, binder, and as a defoaming agent in accordance with good manufacturing practice.

(2) As a component in the manufacture of other food-grade additives.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in
addition to the other information re-
required by the act, the following:

(1) The common or usual name of the acid or acids contained therein.

(2) The words “food grade,” in jux-
taposition with and equally as promi-
nent as the name of the acid.


§ 172.861 Cocoa butter substitute from coconut oil, palm kernel oil, or both oils.

The food additive, cocoa butter sub-
stitute from coconut oil, palm kernel oil, or both oils, may be safely used in food in accordance with the following conditions:

(a) Cocoa butter substitute from co-
conut oil, palm kernel oil (CAS Reg.
No. 85665–33–4), or both oils is a mixture
of triglycerides. It is manufactured by
esterification of glycerol with food-
grade fatty acids (complying with
§ 172.860) derived from edible coconut
oil, edible palm kernel oil, or both oils.

(b) The ingredient meets the fol-
lowing specifications:

Acid number: Not to exceed 0.5.
Saponification number: 220 to 260.
Iodine number: Not to exceed 3.
Melting range: 30 to 44°C.

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

(1) As coating material for sugar,
table salt, vitamins, citric acid, suc-
cinic acid, and spices; and

(2) In compound coatings, cocoa
creams, cocoa-based sweets, toffees,
caramel masses, and chewing sweets as
defined in §170.3 (n)(9) and (n)38) of
this chapter, except that the ingredient
may not be used in a standardized food
unless permitted by the standard of
identity.

(d) The ingredient is used in accord-
ance with current good manufacturing
practice and in an amount not to ex-
ceed that reasonably required to ac-
complish the intended effect.


§ 172.862 Oleic acid derived from tall oil fatty acids.

The food additive oleic acid derived
from tall oil fatty acids may be safely
used in food and as a component in the
manufacture of food-grade additives in
accordance with the following pre-
scribed conditions:

(a) The additive consists of purified oleic acid separated from refined tall oil fatty acids.

(b) The additive meets the following specifications:

(1) Specifications for oleic acid pre-
scribed in the “Food Chemicals
Codex.” 3d Ed. (1981), pp. 207–208, which
is incorporated by reference, except
that titer (solidification point) shall
not exceed 13.5°C and unsaponifiable
matter shall not exceed 0.5 percent.
Copies of the material incorporated by
reference may be obtained from the
National Academy Press, 2101 Constitu-
tion Ave. NW., Washington, DC 20418,
or may be examined at the National
Archives and Records Administration
(NARA). For information on the avail-
ability 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.

(2) The resin acid content does not
exceed 0.01 as determined by ASTM
method D1240–82, “Standard Test Meth-
od for Rosin Acids in Fatty Acids,”
which is incorporated by reference.
Copies may be obtained from the Amer-
ican Society for Testing Materials, 100
Barr Harbor Dr., West Conshohocken,
Philadelphia, PA 19428-2959, 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.

(3) The requirements for absence of
chick-edema factor as prescribed in
§172.860.

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

(1) In foods as a lubricant, binder,
and deofoaming agent in accordance
with good manufacturing practice.

(2) As a component in the manufac-
ture of other food-grade additives.

(d) To assure safe use of the additive,
the label and labeling of the additive
and any premix thereof shall bear, in
addition to the other information required by the Act, the following:

(1) The common or usual name of the acid.

(2) The words “food grade” in juxtaposition with and equally as prominent as the name of the acid.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.863 Salts of fatty acids.

The food additive salts of fatty acids may be safely used in food and in the manufacture of food components in accordance with the following prescribed conditions:

(a) The additive consists of one or any mixture of two or more of the aluminum, calcium, magnesium, potassium, and sodium salts of the fatty acids conforming with §172.860 and/or oleic acid derived from tall oil fatty acids conforming with §172.862.

(b) The food additive is used or intended for use as a binder, emulsifier, and anticaking agent in food in accordance with good manufacturing practice.

(c) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the Act, the following:

(1) The common or usual name of the fatty acid salt or salts contained therein.

(2) The words “food grade,” in juxtaposition with and equally as prominent as the name of the salt.

§ 172.864 Synthetic fatty alcohols.

Synthetic fatty alcohols may be safely used in food and in the synthesis of food components in accordance with the following prescribed conditions:

(a) The food additive consists of any one of the following fatty alcohols:

1. Hexyl, octyl, decyl, lauryl, myristyl, cetyl, and stearyl; manufactured by fractional distillation of alcohols obtained by a sequence of oxidation, hydrolysis, and catalytic hydrogenation (catalyst consists of copper, chromium, and nickel) of organo-aluminums generated by the controlled reaction of low molecular weight trialkylaluminum with purified ethylene (minimum 99 percent by volume C₂H₄), and utilizing an external coolant such that these alcohols meet the specifications prescribed in paragraph (a)(1)(i) and (iii) of this section.

2. n-Octyl; manufactured by the hydrodimerization of 1,3-butadiene, followed by catalytic hydrogenation of the resulting dienol, and distillation to produce n-octyl alcohol with a minimum purity of 99 percent. The analytical method for n-octyl alcohol entitled “Test Method [Normal-octanol]” dated October 2003, and printed by Kuraray Co., Ltd., is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the Office of Food Additive Safety, 5100 Paint Branch Pkwy., College Park, MD 20740, or you may examine a copy at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 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/
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(b) The hydrocarbon solvent used in the process described in paragraph (a)(1) of this section is a mixture of liquid hydrocarbons essentially paraffinic in nature, derived from petroleum and refined to meet the specifications described in paragraph (b)(1) of this section when subjected to the procedures described in paragraph (b)(2) and (3) of this section.

(1) The hydrocarbon solvent meets the following specifications:

(i) Boiling-point range: 175 °C–275 °C.

(ii) Ultraviolet absorbance limits as follows:

<table>
<thead>
<tr>
<th>Wavelength (mill indoors)</th>
<th>Maximum absorbance per centimeter optical path length</th>
</tr>
</thead>
<tbody>
<tr>
<td>280–289</td>
<td>0.15</td>
</tr>
<tr>
<td>290–299</td>
<td>0.12</td>
</tr>
<tr>
<td>300–359</td>
<td>0.05</td>
</tr>
<tr>
<td>360–400</td>
<td>0.02</td>
</tr>
</tbody>
</table>

(2) Use ASTM method D86–82, “Standard Method for Distillation of Petroleum Products,” which is incorporated by reference, to determine boiling point range. Copies of the material incorporated by reference may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428–2959, 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_regulations/code_of_federal_regulations/ibr_locations.html.

(3) The analytical method for determining ultraviolet absorbance limits is as follows:

**GENERAL INSTRUCTIONS**

All glassware should be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure, it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of hydrocarbon solvents samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

**APPARATUS**

Chromatographic tube. 450 millimeters in length (packing section), inside diameter 19 millimeters ±1 millimeter, equipped with a wad of clean Pyrex brand filtering wool (Corning Glass Works Catalog No. 3950 or equivalent). The tube shall contain a 250-milliliter reservoir and a 2-milliliter tetrafluoroethylene polymer stopcock at the opposite end. Overall length of the tube is 670 millimeters.

Stainless steel rod. 2 feet in length, 2 to 4 millimeters in diameter.

Vacuum oven. Similar to Labline No. 3610 but modified as follows: A copper tube one-fourth inch in diameter and 13 inches in length is bent to a right angle at the 4-inch point and plugged at the opposite end; eight copper tubes one-eighth inch in diameter and 5 inches in length are silver soldered in drilled holes (one-eighth inch in diameter) to the one-fourth-inch tube, one on each side at the 5-, 7.5-, 10- and 12.5-inch points; the one-eighth-inch copper tubes are bent to conform with the inner periphery of the oven.

Beakers. 250-milliliter and 500-milliliter capacity.

Graduated cylinders. 25-milliliter, 50-milliliter, and 150-milliliter capacity.

Tuberculin syringe. 1-milliliter capacity, with 3-inch, 22-gauge needle.

Volumetric flask. 5-milliliter capacity.

Spectrophotometric cells. Fused quartz ground glass stoppered cells, optical path length in the range of 1.000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance difference.

Spectrophotometer. Spectral range 250 millimicrons–400 millimicrons with spectral slit width of 2 millimicrons or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy, ±0.05 at 0.4 absorbance.

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Wavelength repeatability, ±0.2 millimicron.
Wavelength accuracy, ±1.0 millimicron.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 pounds per square inch. (For use with regulator and valve to control flow at 5 pounds per square inch.)

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane, benzene, hexane, and 1,2-dichloroethane designated in the list following this paragraph shall pass the following test:

To the specified quantity of solvent in a 250-milliliter beaker, add 1 milliliter of purified n-hexadecane and evaporate in the vacuum oven under a stream of nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 5-milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.) Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 5 milliliters volume. Determine the absorbance in the 1-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue shall not exceed 0.02 per centimeter path length between 300 and 359 millimicrons. The absorbance per centimeter path length shall not exceed 0.00 in this range. If necessary, n-hexadecane may be purified by percolation through activated silica gel or by distillation.

Silica gel, 28–200 mesh (Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent). Activate as follows: Weigh about 900 grams into a 1-gallon bottle, add 100 milliliters of de-ionized water, seal the bottle and shake and roll at intervals for 1 hour. Allow to equilibrate overnight in the sealed bottle. Activate the gel at 150°C for 16 hours, in a 2-inch × 7-inch × 12-inch porcelain pan loosely covered with aluminum foil, cool in a dessicator, transfer to a bottle and seal.

PROCEDURE

Determination of ultraviolet absorbance. Before proceeding with the analysis of a sample determine the absorbance in a 1-centimeter path cell for the reagent blank by carrying out the procedure without a sample. Record the absorbance in the wavelength range of 280 to 400 millimicrons. Typical reagent blank absorbance in this range should not exceed 0.04 in the 280 to 299 millimicron range, 0.02 in the 300 to 359 millimicron range, and 0.01 in the 360 to 400 millimicron range. If the characteristic benzene peaks in the 250 to 260 millimicron region are present, remove the benzene by the procedure described above under “Reagents and Materials,” “Organic Solvents,” and record absorbance again.

Transfer 50 grams of silica gel to the chromatographic tubing for sample analysis. Raise and drop the column on a semisoft, clean surface for about 1 minute to settle the gel. Pour 100 milliliters of hexane into the column with the stopcock open and allow to drain to about one-half inch above the gel. Turn off the stopcock and allow the column to cool for 30 minutes. After cooling, vibrate the column to eliminate air and stir the top 1 to 2 inches with a small diameter stainless steel rod. Take care not to get the gel above the liquid and onto the sides of the column.
§ 172.867 Olestra.

Olestra, as identified in this section, may be safely used in accordance with the following conditions:

(a) Olestra is a mixture of octa-, hepta-, and hexa-esters of sucrose with fatty acids derived from edible fats and oils or fatty acid sources that are generally recognized as safe or approved for use as food ingredients. The chain lengths of the fatty acids are no less than 12 carbon atoms.

(b) Olestra meets the specifications of the Food Chemicals Codex, 4th edition, 1st supplement (1997), pp. 33-35, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418 (Internet address http://www.nap.edu). Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 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.

(c) Synthetic fatty alcohols may be used as follows:

(1) As substitutes for the corresponding naturally derived fatty alcohols permitted in food by existing regulations in this part or part 173 of this chapter provided that the use is in compliance with any prescribed limitations.

(2) As substitutes for the corresponding naturally derived fatty alcohols used as intermediates in the synthesis of food additives and other substances permitted in food.

§ 172.866 Synthetic glycerin produced by the hydrogenolysis of carbohydrates.

Synthetic glycerin produced by the hydrogenolysis of carbohydrates may be safely used in food, subject to the provisions of this section:

(a) It shall contain not in excess of 0.2 percent by weight of a mixture of butanetriols.

(b) It is used or intended for use in an amount not to exceed that reasonably required to produce its intended effect.

§ 172.867 Olestra.

Olestra, as identified in this section, may be safely used in accordance with the following conditions:

(a) Olestra is a mixture of octa-, hepta-, and hexa-esters of sucrose with fatty acids derived from edible fats and oils or fatty acid sources that are generally recognized as safe or approved for use as food ingredients. The chain lengths of the fatty acids are no less than 12 carbon atoms.

(b) Olestra meets the specifications of the Food Chemicals Codex, 4th edition, 1st supplement (1997), pp. 33-35, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418 (Internet address http://www.nap.edu). Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 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.

(c) Synthetic fatty alcohols may be used as follows:

(1) As substitutes for the corresponding naturally derived fatty alcohols permitted in food by existing regulations in this part or part 173 of this chapter provided that the use is in compliance with any prescribed limitations.

(2) As substitutes for the corresponding naturally derived fatty alcohols used as intermediates in the synthesis of food additives and other substances permitted in food.

§ 172.866 Synthetic glycerin produced by the hydrogenolysis of carbohydrates.

Synthetic glycerin produced by the hydrogenolysis of carbohydrates may be safely used in food, subject to the provisions of this section:

(a) It shall contain not in excess of 0.2 percent by weight of a mixture of butanetriols.

(b) It is used or intended for use in an amount not to exceed that reasonably required to produce its intended effect.

§ 172.867 Olestra.

Olestra, as identified in this section, may be safely used in accordance with the following conditions:

(a) Olestra is a mixture of octa-, hepta-, and hexa-esters of sucrose with fatty acids derived from edible fats and oils or fatty acid sources that are generally recognized as safe or approved for use as food ingredients. The chain lengths of the fatty acids are no less than 12 carbon atoms.

(b) Olestra meets the specifications of the Food Chemicals Codex, 4th edition, 1st supplement (1997), pp. 33-35, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418 (Internet address http://www.nap.edu). Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 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.

(c) Synthetic fatty alcohols may be used as follows:

(1) As substitutes for the corresponding naturally derived fatty alcohols permitted in food by existing regulations in this part or part 173 of this chapter provided that the use is in compliance with any prescribed limitations.

(2) As substitutes for the corresponding naturally derived fatty alcohols used as intermediates in the synthesis of food additives and other substances permitted in food.

§ 172.866 Synthetic glycerin produced by the hydrogenolysis of carbohydrates.

Synthetic glycerin produced by the hydrogenolysis of carbohydrates may be safely used in food, subject to the provisions of this section:

(a) It shall contain not in excess of 0.2 percent by weight of a mixture of butanetriols.

(b) It is used or intended for use in an amount not to exceed that reasonably required to produce its intended effect.

§ 172.867 Olestra.

Olestra, as identified in this section, may be safely used in accordance with the following conditions:

(a) Olestra is a mixture of octa-, hepta-, and hexa-esters of sucrose with fatty acids derived from edible fats and oils or fatty acid sources that are generally recognized as safe or approved for use as food ingredients. The chain lengths of the fatty acids are no less than 12 carbon atoms.

(b) Olestra meets the specifications of the Food Chemicals Codex, 4th edition, 1st supplement (1997), pp. 33-35, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418 (Internet address http://www.nap.edu). Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 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.
§ 172.868

(c) Olestra may be used in place of fats and oils in prepackaged ready-to-eat savory (i.e., salty or piquant but not sweet) snacks and prepackaged, unpopped popcorn kernels that are ready-to-heat. In such foods, the additive may be used in place of fats and oils for frying or baking, in dough conditioners, in sprays, in filling ingredients, or in flavors.

(d) To compensate for any interference with absorption of fat soluble vitamins, the following vitamins shall be added to foods containing olestra: 1.9 milligrams alpha-tocopherol equivalents per gram olestra; 51 retinol equivalents per gram olestra (as retinyl acetate or retinyl palmitate); 12 IU vitamin D per gram olestra; and 8 μg vitamin K per gram olestra.

(e)(1) Vitamins A, D, E, and K present in foods as a result of the requirement in paragraph (d) of this section shall be declared in the listing of ingredients. Such vitamins shall not be considered in determining nutrient content for the nutritional label or for any nutrient claims, express or implied.

(i) An asterisk shall follow vitamins A, D, E, and K in the listing of ingredients;

(ii) The asterisk shall appear as a superscript following each vitamin;

(iii) Immediately following the ingredient list an asterisk and statement, “Dietarily insignificant” shall appear prominently and conspicuously as specified in §101.2(c) of this chapter;

(2) Olestra shall not be considered as a source of fat or calories for purposes of §§101.9 and 101.13 of this chapter.

§ 172.869

Sucrose oligoesters.

Sucrose oligoesters, as identified in this section, may be safely used in accordance with the following conditions:

(a) Sucrose oligoesters consist of mixtures of sucrose fatty acid esters with an average degree of esterification ranging from four to seven. It is produced by interesterification of sucrose with methyl esters of fatty acids derived from edible fats and oils (including hydrogenated fats and oils). The only solvents which may be used in the preparation of sucrose oligoesters are dimethyl sulfoxide, isobutyl alcohol, and those solvents generally recognized as safe in food.

(b) Sucrose oligoesters meet the specifications in the methods listed in the table in this paragraph. The methods cited for determining compliance with each specification are incorporated by reference, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the methods may be examined at the Center for Food Safety and Applied Nutrition’s Library, room 1C–100, 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. Copies of the methods are available from the sources listed in the table in this paragraph:

§ 172.868 Ethyl cellulose.

The food additive ethyl cellulose may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is a cellulose ether containing ethoxy (OC₂H₅) groups attached by an ether linkage and containing on an anhydrous basis not more than 2.6 ethoxy groups per anhydroglucose unit.

(b) It is used or intended for use as follows:

(1) As a binder and filler in dry vitamin preparations.

(2) As a component of protective coatings for vitamin and mineral tablets.

(3) As a fixative in flavoring compounds.
### Specifications and Methods

<table>
<thead>
<tr>
<th>Specification</th>
<th>Limit</th>
<th>Method Cited</th>
<th>Source for Obtaining Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>(3) Tetra-, penta-, hexa-, and hepta-esters.</td>
<td>Not less than 50%</td>
<td>Do.</td>
<td>Do.</td>
</tr>
<tr>
<td>(4) Octa-esters</td>
<td>Not more than 40%</td>
<td>Do.</td>
<td>Do.</td>
</tr>
<tr>
<td>(9) Residual Dimethyl Sulfoxide</td>
<td>Not more than 2.0 milligrams/kilogram.</td>
<td>Do.</td>
<td>Do.</td>
</tr>
<tr>
<td>(10) Residual Isobutyl Alcohol</td>
<td>Not more than 10 milligrams/kilogram.</td>
<td>Do.</td>
<td>Do.</td>
</tr>
</tbody>
</table>

### Notes

(c) The additive is used as an emulsifier (as defined in §170.3(o)(8) of this chapter) or stabilizer (as defined in §170.3(o)(28) of this chapter) in chocolate and in butter-substitute spreads, at a level not to exceed 2.0 percent; except that the additive may not be used in a standardized food unless permitted by the standard of identity.

§ 172.870 Hydroxypropyl cellulose.

The food additive hydroxypropyl cellulose may be safely used in food, except standardized foods that do not provide for such use, in accordance with the following prescribed conditions:

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

1. A cellulose ether containing propylene glycol groups attached by an ether linkage which contains, on an anhydrous basis, not more than 4.6
hydroxypropyl groups per anhydroglucose unit. The additive has a minimum viscosity of 145 centipoises for 10 percent by weight aqueous solution at 25 °C.

(2) A cellulose ether containing propylene glycol groups attached by an ether linkage having a hydroxypropoxy (OC$_3$H$_6$OH) content of 5 to 16 percent weight in weight (w/w) on an anhydrous basis, i.e., 0.1 to 0.4 hydroxypropyl groups per anhydroglucose unit. The common name for this form of the additive is low substituted hydroxypropyl cellulose.

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

(1) The additive identified in paragraph (a)(1) of this section is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener, in accordance with good manufacturing practice.

(2) The additive identified in paragraph (a)(2) of this section is used or intended for use as a binder and disintegrator in tablets or wafers containing dietary supplements of vitamins and/or minerals. The additive is used in accordance with good manufacturing practice.

[46 FR 50065, Oct. 9, 1981]

§ 172.872 Methyl ethyl cellulose.

The food additive methyl ethyl cellulose may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a cellulose ether having the general formula [C$_6$H$_5$(10-x-y)O$_3$(CH$_3$)$_x$(C$_2$H$_5$)$_y$]$_n$, where $x$ is the number of methyl groups and $y$ is the number of ethyl groups. The average value of $x$ is 0.3 and the average value of $y$ is 0.7.

(b) The additive meets the following specifications:

(1) The methoxy content shall be not less than 3.5 percent and not more than 6.5 percent, calculated as OCH$_3$, and the ethoxy content shall be not less than 14.5 percent and not more than 19 percent, calculated as OC$_2$H$_5$, both measured on the dry sample.

(2) The viscosity of an aqueous solution, 2.5 grams of the material in 100 milliliters of water, at 20 °C, is 20 to 60 centipoises.

(3) The ash content on a dry basis has a maximum of 0.6 percent.

(c) The food additive is used as an aerating, emulsifying, and foaming agent, in an amount not in excess of that reasonably required to produce its intended effect.

§ 172.874 Hydroxypropyl methylcellulose.

The food additive hydroxypropyl methylcellulose (CAS Reg. No. 9004–65–3) may be safely used in food, except in standardized foods which do not provide for such use if:

(a) The additive complies with the definition and specifications prescribed in the National Formulary, 12th edition.

(b) It is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener, in accordance with good manufacturing practice.

(c) To insure safe use of the additive, the container of the additive, in addition to being labeled as required by the general provisions of the act, shall be accompanied by labeling which contains adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 38273, Aug. 31, 1982]

§ 172.876 Castor oil.

The food additive castor oil may be safely used in accordance with the following conditions:

(a) The additive meets the specifications of the United States Pharmacopeia XX (1980).

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

Use and Limitations

Hard candy production—As a release agent and antisticking agent, not to exceed 500 parts per million in hard candy.

Vitamin and mineral tablets—As a component of protective coatings.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.878 White mineral oil.

White mineral oil may be safely used in food in accordance with the following conditions:
Food and Drug Administration, HHS § 172.878

(a) White mineral oil is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature obtained from petroleum. It is refined to meet the following specifications:

1. It meets the test requirements of the United States Pharmacopeia XX (1980) for readily carbonizable substances (page 532).
2. It meets the test requirements of U.S.P. XVII for sulfur compounds (page 400).

(b) White mineral oil may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the Act, in an amount not greater than that required to produce its intended effect.

(c) White mineral oil is used or intended for use as follows:

<table>
<thead>
<tr>
<th>Use</th>
<th>Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. As a release agent, binder, and lubricant in or on capsules and tablets containing concentrates of flavoring, spices, condiments, and nutrients intended for addition to food, excluding confectionery.</td>
<td>Not to exceed 0.6% of the capsule or tablet.</td>
</tr>
<tr>
<td>2. As a release agent, binder, and lubricant in or on capsules and tablets containing food for special dietary use.</td>
<td>Not to exceed 0.6% of the capsule or tablet.</td>
</tr>
<tr>
<td>3. As a float on fermentation fluids in the manufacture of vinegar and wine to prevent or retard access of air, evaporation, and wild yeast contamination during fermentation.</td>
<td>In an amount not to exceed good manufacturing practice.</td>
</tr>
<tr>
<td>4. As a defoamer in food.</td>
<td>In accordance with § 173.340 of this chapter.</td>
</tr>
<tr>
<td>5. In bakery products, as a release agent and lubricant.</td>
<td>Not to exceed 0.15% of bakery products.</td>
</tr>
<tr>
<td>6. In dehydrated fruits and vegetables, as a release agent.</td>
<td>Not to exceed 0.22% of dehydrated fruits and vegetables.</td>
</tr>
<tr>
<td>7. In egg white solids, as a release agent.</td>
<td>Not to exceed 0.1% of egg white solids.</td>
</tr>
<tr>
<td>8. On raw fruits and vegetables, as a protective coating.</td>
<td>In an amount not to exceed good manufacturing practice.</td>
</tr>
<tr>
<td>9. In frozen meat, as a component of hot-melt coating.</td>
<td>Not to exceed 0.095% of meat.</td>
</tr>
<tr>
<td>10. As a protective float on brine used in the curing of pickles.</td>
<td>In an amount not to exceed good manufacturing practice.</td>
</tr>
<tr>
<td>11. In molding starch used in the manufacture of confectionery.</td>
<td>Not to exceed 0.3 percent in the molding starch.</td>
</tr>
<tr>
<td>12. As a release agent, binder, and lubricant in the manufacture of yeast</td>
<td>Not to exceed 0.15 percent of yeast.</td>
</tr>
<tr>
<td>13. As an antidusting agent in sorbit acid for food use.</td>
<td>Not to exceed 0.25 percent in the sorbit acid.</td>
</tr>
<tr>
<td>14. As release agent and as sealing and polishing agent in the manufacture of confectionery.</td>
<td>Not to exceed 0.2 percent of confectionery. Applied at a level of no more than 0.02 percent by weight of grain.</td>
</tr>
<tr>
<td>15. As a dust control agent for wheat, corn, soybean, barley, rice, oats, and sorghum.</td>
<td>ISO 100 oil viscosity (100 centistokes (cSt) at 100°F) applied at a level of no more than 0.08 percent by weight of the rice grain.</td>
</tr>
<tr>
<td>16. As a dust control agent for rice.</td>
<td></td>
</tr>
</tbody>
</table>

§ 172.880 Petrolatum.

Petrolatum may be safely used in food, subject to the provisions of this section.
(a) Petrolatum complies with the specifications set forth in the United States Pharmacopeia XX (1980) for white petrolatum or in the National Formulary XV (1980) for petrolatum.
(b) Petrolatum meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in §172.886(b):

<table>
<thead>
<tr>
<th>Millimicrons</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>280–289</td>
<td>0.25</td>
</tr>
<tr>
<td>290–299</td>
<td>0.20</td>
</tr>
<tr>
<td>300–359</td>
<td>0.14</td>
</tr>
<tr>
<td>360–400</td>
<td>0.04</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Use</th>
<th>Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with petrolatum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In bakery products; as release agent and lubricant</td>
<td>With white mineral oil, not to exceed 0.15 percent of bakery product.</td>
</tr>
<tr>
<td>In confectionery; as release agent and as sealing and polishing agent</td>
<td>Not to exceed 0.2 percent of confectionery.</td>
</tr>
<tr>
<td>In dehydrated fruits and vegetables; as release agent</td>
<td>Not to exceed 0.02 percent of dehydrated fruits and vegetables.</td>
</tr>
<tr>
<td>In egg white solids; as release agent</td>
<td>Not to exceed 0.1 percent of egg white solids.</td>
</tr>
<tr>
<td>On raw fruits and vegetables; as protective coating</td>
<td>In an amount not to exceed good manufacturing practice.</td>
</tr>
<tr>
<td>In beet sugar and yeast; as defoaming agent</td>
<td>As prescribed in §173.340 of this chapter.</td>
</tr>
</tbody>
</table>

(d) Petrolatum may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the Act, in an amount not greater than that required to produce its intended effect.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.882 Synthetic isoparaffinic petroleum hydrocarbons.

Synthetic isoparaffinic petroleum hydrocarbons may be safely used in food, in accordance with the following conditions:
(a) They are produced by synthesis from petroleum gases and consist of a mixture of liquid hydrocarbons meeting the following specifications:


- Ultraviolet absorbance: 280–319 millimicrons—1.5 maximum, 320–329 millimicrons—0.08 maximum, 330–350 millimicrons—0.05 maximum. Nonvolatile residual: 0.002 gram per 100 milliliters maximum.

- Synthetic isoparaffinic petroleum hydrocarbons containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. The ultraviolet absorbance shall be determined by the procedure described for application of mineral oil, disregarding the last sentence of the procedure, under “Specifications” on page 66 of the “Journal of the Association of Official Analytical Chemists,” Volume 45 (February 1962), 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, 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. If hydrocarbons boiling below 250 °F, the nonvolatile residue shall be determined by ASTM method D1153–78, “Standard Test Method for Nonvolatile Matter in Volatile Solvents for Use in Paint, Varnish, Lacquer, and Related Products;” for those boiling above 121 °C, ASTM method D1981–89, “Standard Test Method for Existant Gum in Fuels by Jet Evaporation” shall be used. These methods are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100

21 CFR Ch. I (4–1–11 Edition)
§ 172.886 Petroleum wax.

Petroleum wax may be safely used in or on food, in accordance with the following conditions:

(a) Petroleum wax is a mixture of solid hydrocarbons, paraffinic in nature, derived from petroleum, and refined to meet the specifications prescribed by this section.

(b) Petroleum wax meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in this paragraph.

<table>
<thead>
<tr>
<th>Wavelength µm</th>
<th>Maximum absorbance per centimeter optical path length</th>
</tr>
</thead>
<tbody>
<tr>
<td>280–289</td>
<td>4.0</td>
</tr>
<tr>
<td>290–299</td>
<td>3.3</td>
</tr>
<tr>
<td>300–329</td>
<td>2.3</td>
</tr>
<tr>
<td>330–360</td>
<td>0.8</td>
</tr>
</tbody>
</table>

(c) The additive is used as follows:

<table>
<thead>
<tr>
<th>Use</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>As a coating on shell eggs</td>
<td>In an amount not to exceed good manufacturing practice.</td>
</tr>
<tr>
<td>As a defoamer in processing</td>
<td>Complying with § 173.340 of this chapter.</td>
</tr>
<tr>
<td>beet sugar and yeast.</td>
<td></td>
</tr>
<tr>
<td>As a float on fermentation</td>
<td>In an amount not to exceed good manufacturing practice.</td>
</tr>
<tr>
<td>fluids in the manufacture of</td>
<td></td>
</tr>
<tr>
<td>vinegar and wine to prevent</td>
<td></td>
</tr>
<tr>
<td>or retard access of air,</td>
<td></td>
</tr>
<tr>
<td>evaporation, and contamination with wild organisms during fermentation.</td>
<td></td>
</tr>
<tr>
<td>In the froth-flotation cleaning of vegetables.</td>
<td>Do.</td>
</tr>
<tr>
<td>As a component of insecticide</td>
<td></td>
</tr>
<tr>
<td>formulations used in compliance with § 170 through 189 of this chapter.</td>
<td>Do.</td>
</tr>
</tbody>
</table>

Analytical Specification for Petroleum Wax

General Instructions

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified iso-octane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of wax samples in handling and to assure absence of any extraneous material arising from inadequate packing is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

Apparatus

Separatory funnels. 250-milliliter, 500-milliliter, 1,000-milliliter, and preferably 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Reservoir. 500-milliliter capacity, equipped with a 24/40 standard taper male fitting at the opposite end. (Overall length of 24/40 standard taper male fitting is 235 millimeters, inside diameter to be 15.7 millimeters.) The female fitting should be equipped with glass hooks.

Chromatographic tube. 180 millimeters in length, inside diameter of 15.7 millimeters ±0.1 millimeter, equipped with a 24/40 standard taper female fitting at the opposite end. (Overall length of column with female joint is 235 millimeters.) The female fitting should be equipped with glass hooks.

Disc. Tetrafluoroethylene polymer 2-inch diameter disc approximately 3⁄16-inch thick with a hole bored in the center to closely fit the stem of the chromatographic tube.

Heating jacket. Conical, for 500-milliliter separatory funnel. (Used with variable transformer heat control.)

Suction flask. 250-milliliter or 500-milliliter filter flask.

Condenser. 24/40 joints, fitted with a drying tube, length optional.

Evaporation flask (optional). 250-milliliter or 500-milliliter capacity all-glass flask equipped with a 24/40 standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Vacuum distillation assembly. All glass (for purification of dimethyl sulfoxide); 2-liter distillation flask with heating mantle; Vigreaux vacuum-jacketed condenser (or equivalent) about 45 centimeters in length and distilling head with separable cold finger condenser. Use of tetrafluoroethylene polymer sleeves on the glass joints will prevent freezing. Do not use grease on stopcocks or joints.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5,000 centimeters ±0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1,000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Spectral range 250 millimicrons–400 millimicrons with spectral slit width of 2 millimicrons or less, under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy, ±0.05 at 0.4 absorbance.

Wavelength repeatability, ±0.2 millimicron.

Wavelength accuracy, ±0.2 millimicron.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

Reagents and Materials

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The iso-octane, benzene, acetone, and methyl alcohol designated in the list following this paragraph shall pass the following test:

To the specified quantity of solvent in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified n-hexadecane and evaporate on the steam bath under a stream of nitrogen (a) loose aluminum foil jacket around
the flask will speed evaporation. Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 10-milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.) Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case, the solvent and n-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 25 milliliters volume. Determine the absorbance in the 5-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue (except for methyl alcohol) shall not exceed 0.01 per centimeter path length between 280 and 400 μm. For methyl alcohol this absorbance value shall be 0.00.

*Isooctane (2,2,4-trimethylpentane).* Use 180 milliliters for the test described in the preceding paragraph. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Company, Baltimore, Maryland, or equivalent) about 90 centimeters in length and 5 centimeters to 8 centimeters in diameter.

*Benzenes.* A.C.S. reagent grade. Use 150 milliliters for the test. Purify, if necessary, by distillation or otherwise.

*Acetone.* A.C.S. reagent grade. Use 200 milliliters for the test. Purify, if necessary, by distillation.

Eluting mixtures:

1. **10 percent benzene in isooctane.** Pipet 50 milliliters of benzene into a 250-milliliter glass-stoppered volumetric flask and adjust to volume with isooctane, with mixing.

2. **20 percent benzene in isooctane.** Pipet 50 milliliters of benzene into a 250-milliliter glass-stoppered volumetric flask, and adjust to volume with isooctane, with mixing.

3. **Acetone-benzene-water mixture.** Add 20 milliliters of water to 380 milliliters of acetone and 200 milliliters of benzene, and mix.

*n-Hexadecane, 99 percent olefin-free.* Dilute 1.0 milliliter of n-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference point between 280 μm–400 μm. The absorbance per centimeter path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

*Methyl alcohol.* A.C.S. reagent grade. Use 10.0 milliliters of methyl alcohol. Purify, if necessary, by distillation.

*Dimethyl sulfoxide.* Pure grade, clear, water-white, m.p. 18°C minimum. Dilute 120 milliliters of dimethyl sulfoxide with 240 milliliters of distilled water in a 500-milliliter separatory funnel, mix and allow to cool for 5–10 minutes. Add 40 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second 500-milliliter separatory funnel and repeat the extraction with 40 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 40-milliliter extractives three times with 50-milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see *Sodium sulfate under “Reagents and Materials” for preparation of filter), into a 250-milliliter Erlenmeyer flask, or optionally into the evaporating flask. Wash the first separatory funnel with the second 40-milliliter isooctane extractive, and pass through the sodium sulfate into the flask. Then wash the second and first separatory funnels successively with a 10-milliliter portion of isooctane, and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of n-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10-milliliter portion of isooctane and reevaporate to 1 milliliter of hexadecane. Again, add 10 milliliters of isooctane to the residue and evaporate to 1 milliliter of hexadecane to insure complete removal of all volatile materials. Dissolve the 1 milliliter of hexadecane in isooctane and make to 25-milliliter volume. Determine the absorbance. The absorbance of the solution should not exceed 0.02 per centimeter path length in the 280 μm–400 μm range. (Note. Difficulty in meeting this absorbance specification may be due to organic impurities in the distilled water. Repetition of the test omitting the dimethyl sulfoxide will disclose their presence. If necessary to meet the specification, purify the water by redistillation, passage through an ion-exchange resin, or otherwise.) Purify, if necessary, by the following procedure: To 1,500 milliliters of dimethyl sulfoxide in a 2-liter glass-stoppered flask, add 6.0 milliliters of phosphoric acid and 50 grams of Norit A (decolorizing carbon, alkaline) or equivalent. Stopper the flask, and with the use of a magnetic stirrer (tetrfluoroethylene polymer coated bar) stir the solvent for 15 minutes. Filter the dimethyl sulfoxide through four thicknesses of fluted paper (18.5 centimeters, Schleicher & Schuell, No. 597, or equivalent). If the initial filtrate contains carbon fines, refilter through the same filter until a clear filtrate is obtained. Protect the sulfoxide from air and moisture during this operation by covering the solvent in the funnel and collection flask with a layer of isooctane. Transfer the
filtrate to a 2-liter separatory funnel and draw off the dimethyl sulfoxide into the 2-
liter distillation flask of the vacuum distillation assembly and distill at approxi-
matel 100° C for 2 hours. Discard the first 200-milliliter fraction of the distillate and replace the distillate collection flask with a clean one. Continue the distillation until about 1 liter of the sulfoxide has been collected.

At completion of the distillation, the reagent should be stored in glass-stopped bottles since it is very hygroscopic and will react with some metal containers in the presence of air.

Phosphoric acid. 85 percent A.C.S. reagent grade.

Sodium borohydride. 98 percent.

Magnesium oxide (Sea Sorb 43, Food Machinery Company, Westraco Division, distributed by chemical supply firms, or equivalent). Place 100 grams of the magnesium oxide in a large beaker, add 700 milliliters of distilled water to make a thin slurry, and heat on a steam bath for 30 minutes with intermittent stirring. Stir well initially to insure that all the absorbent is completely wetted. Using a Buchner funnel and a filter paper (Schleicher & Schuell No. 597, or equivalent) of suitable diameter, filter with suction. Continue suction until water no longer drips from the funnel. Transfer the absorbent to a glass trough lined with aluminum foil (free from rolling oil). Break up the magnesia with a clean spatula and spread out the absorbent on the aluminum foil in a layer about 1 centimeter to 2 centimeters thick. Dry for 24 hours at 160° C ± 1° C. Pulverize the magnesia with mortar and pestle. Sieve the pulverized absorbent between 60–180 mesh. Use the magnesium retained on the 180-mesh sieve.

Celite 545. Johns-Manville Company, diatomaceous earth, or equivalent.

Magnesium oxide-Celite 545 mixture (2+ 1) by weight. Place the magnesium oxide (60–180 mesh) and the Celite 545 in 2 to 1 proportions, respectively, by weight in a glass-stoppered flask large enough for adequate mixing. Shake vigorously for 10 minutes. Transfer the mixture to a glass trough lined with aluminum foil (free from rolling oil) and spread it out on a layer about 1 centimeter to 2 centimeters thick. Reheat the mixture at 150° C ± 2° C for 2 hours, and store in a tightly closed flask.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30-milliliter coarse, tinned-glass funnel or in a 65-milliliter filter funnel with glass wool plug; wash with successive 15-milliliter portions of the indicated solvent until a 15-milliliter portion of the wash shows 0.00 absorbance per centimeter path length between 280 μm and 400 μm when tested as prescribed under “Organic solvents.” Usually three portions of wash solvent are sufficient.

Before proceeding with analysis of a sample, determine the absorbance in a 5-centimeter path cell between 250 μm and 400 μm for the reagent blank by carrying out the procedure, without a wax sample, at room temperature, recording the spectra after the extraction stage and after the complete procedure as prescribed. The absorbance per centimeter path length following the extraction stage should not exceed 0.040 in the wavelength range from 280 μm to 400 μm; the absorbance per centimeter path length following the complete procedure should not exceed 0.070 in the wavelength range from 280 μm to 299 μm, inclusive, nor 0.045 in the wavelength range from 300 μm to 400 μm. If in either spectrum the characteristic benzene peaks in the 250 μm–360 μm region are present, remove the benzene by the procedure under “Organic solvents” and record absorbance again.

Place 300 milliliters of dimethyl sulfoxide in a 1-liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stoppered.) Add 150 milliliters of isoctane and shake to preequilibrate the solvents. Draw off the individual layers and store in glass-stopped flasks.

Place a representative 1-kilogram sample of wax, or if this amount is not available, the entire sample, in a beaker of a capacity about three times the volume of the sample and heat with occasional stirring on a steam bath until the wax is completely melted and homogeneous. Weigh four 25-gram ± 0.2 gram portions of the melted wax in separate 100-milliliter beakers. Reserve three of the portions for later replicate analyses as necessary. Pour one weighed portion immediately after remelting (on the steam bath) into a 500-milliliter separatory funnel containing 100 milliliters of the pre-equilibrated sulfoxide-phosphoric acid mixture that has been heated in the heating jacket at a temperature just high enough to keep the wax melted. (Note: In preheating the sulfoxide-acid mixture, remove the stopper of the separatory funnel at intervals to release the pressure.)

Promptly complete the transfer of the sample to the funnel in the jacket with portions of the pre-equilibrated isooctane, warming the beaker, if necessary, and using a total volume of just 50 milliliters of the sol-
vent. If the wax comes out of solution during these operations, let the stoppered funnel remain in the jacket until the wax redissolves. (Remove stopper from the funnel at intervals
to release pressure.) When the wax is in solution, remove the funnel from the jacket and shake it vigorously for 2 minutes. Set up three 250-milliliter separatory funnels with each containing 150 milliliters of preequilibrated isooctane. After separation of the liquid phases, allow to cool until the main portion of the wax-isooctane solution begins to come out of the solution. Gently swirl the funnel when precipitation first occurs on the inside surface of the funnel to accelerate this process. Carefully draw off the lower layer, filter it slowly through a thin layer of glass wool fitted loosely in a filter funnel into the first 250-milliliter separatory funnel, and wash in tandem with the 30-milliliter portions of isooctane contained in the 250-milliliter separatory funnels. Shaking time for each wash is 1 minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture, replacing the funnel in the jacket after each extraction to keep the wax in solution and take care to lose none of the solution in filling the sample cell. Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without a wax sample. If the corrected absorbance does not exceed the limits prescribed in this paragraph (b), the wax meets the ultraviolet absorbance specifications. If the corrected absorbance once the path length exceeds the limits prescribed in this paragraph (b), proceed as follows:

Quantitatively transfer the isooctane solution to a 125-milliliter flask equipped with 24/40 joint and evaporate the isooctane on the steam bath under a stream of nitrogen to a volume of 1 milliliter of hexadecane. Add 10 milliliters of methyl alcohol and approximately 0.3 gram of sodium borohydride. Minimize exposure of the borohydride to the atmosphere. A measuring dipper may be used.) Immediately fit a water-cooled condenser equipped with a 24/40 joint and with a drying tube into the flask, mix until the borohydride begins to come out of the solution. Then add 10 milliliters of isooctane and evaporate to a volume of about 2–3 milliliters. Again, add 10 milliliters of isooctane and concentrate to a volume of approximately 5 milliliters. Swirl the flask repeatedly to assure adequate washing of the sodium borohydride residues.

Fit the tetrafluoroethylene polymer disc on the upper part of the stem of the chromatographic tube, then place the tube with the disc on the suction flask and apply the vacuum (approximately 135 millimeters Hg pressure). Weight out 14 grams of the 2:1 magnesium oxide-Celite 545 mixture and pour the adsorbent mixture into the chromatographic tube in approximately 3-centimeter layers. After the addition of each layer, level off the top of the adsorbent with a flat glass rod or metal plunger by pressing down firmly until the adsorbent is well packed. Loosen the topmost few millimeters of each adsorbent layer with the end of a metal rod before the addition of the next layer. Continue packing in this manner until all the 14 grams of the adsorbent is added to the tube. Level off the top of the adsorbent by pressing down firmly with a flat glass rod or metal plunger to make the depth of the adsorbent bed approximately 12.5 centimeters in depth. Turn off the vacuum and remove the suction flask. Fit the 500-milliliter reservoir onto the top of the chromatographic column and prewet the column by passing 100 milliliters of isooctane through the column. Adjust the nitrogen pressure so that the rate of descent of the isooctane coming off of the column is between 2–3 milliliters per minute. Discontinue
pressure just before the last of the isooctane reaches the level of the adsorbent. (Caution: Do not allow the liquid level to recede below the adsorbent level at any time.) Remove the reservoir and decant the 5-milliliter iso-octane concentrate solution onto the column and with slight pressure again allow the liquid level to recede to barely above the adsorbent level. Rapidly complete the transfer similarly with two 5-milliliter portions of isooctane, swirling the flask repeatedly each time to assure adequate washing of the residue. Just before the final 5-milliliter wash reaches the top of the adsorbent, add 100 milliliters of isooctane to the reservoir and continue the percolation at the 2-3 milliliter per minute rate. Just before the last of the isooctane reaches the adsorbent level, add 100 milliliters of 10 percent benzene in isooctane to the reservoir and continue the percolation at the aforementioned rate. Just before the solvent mixture reaches adsorbent level, add 25 milliliters of 20 percent benzene in isooctane to the reservoir and continue the percolation at 2-3 milliliters per minute until all this solvent mixture has been removed from the column. Discard all the elution solvents collected up to this point. Add 300 milliliters of the acetone-benzene-water mixture to the reservoir and percolate through the column to elute the polynuclear compounds. Collect the eluate in a clean 1-liter separation funnel. Allow the column to drain until most of the solvent mixture is removed. Wash the eluate three times with 300-milliliter portions of distilled water, shaking well for each wash. (The addition of small amounts of sodium chloride facilitates separation.) Discard the aqueous layer after each wash. After the final separation, filter the residual benzene through anhydrous sodium sulfate prewashed with benzene (see Sodium sulfate under “Reagents and Materials” for preparation of filter) into a 250-milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the separatory funnel with two additional 20-milliliter portions of benzene which are also filtered through the sodium sulfate. Add 1 milliliter of n-hexadecane and completely remove the benzene by evaporation under nitrogen, using the special procedure to eliminate benzene as previously described under “Organic Solvents.” Quantitatively transfer the residue with isooctane to a 25-milliliter volumetric flask and adjust to volume. Determine the absorbance of the solution in the 5-centimeter path length cells compared to isooctane as reference between 250 μg–400 μg. Correct for any absorbance derived from the reagents as determined by carrying out the procedure without a wax sample. If either spectrum shows the characteristic benzene peaks in the 250 μg–260 μg region, evaporate the solution to remove benzene by the procedure under “Organic Solvents.” Dissolve the residue, transfer quantitatively, and adjust to volume in isooctane in a 25-milliliter volumetric flask. Record the absorbance again. If the corrected absorbance does not exceed the limits prescribed in this paragraph (b), the wax meets the ultraviolet absorbance specifications.

(c) Petroleum wax may contain one or more of the following adjuvants in amounts not greater than that required to produce their intended effect:

(1) Antioxidants permitted in food by regulations issued in accordance with section 409 of the act.

(2) Poly(alkylacrylate) (CAS Reg. No. 27029–57–8), made from long chain (C18–C22) alcohols and acrylic acid, or poly(alkylmethacrylate) (CAS Reg. No. 179529–36–3), made from long chain (C18–C22) methacrylate esters, having:

(i) A number average molecular weight between 40,000 and 100,000;

(ii) A weight average molecular weight (MWw) to number average molecular weight (MWn) ratio (MWw/MWn) of not less than 3; and

(iii) Unreacted alkylacrylate or alkylmethacrylate monomer content not in excess of 14 percent, as determined by a method entitled “Method for Determining Weight-Average and Number-Average Molecular Weight and for Determining Alkylacrylate Monomer Content of Poly(alkylacrylate) used as Processing Aid in Manufacture of Petroleum Wax,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 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 202–741–6930, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Petroleum wax shall contain not more than 1,050 parts per million of poly(alkylacrylate) or poly(alkylmethacrylate) residues as determined by a method entitled “Method for Determining Residual Molecular Weight of Poly(alkylacrylate) and Poly(alkylmethacrylate).”
Level of Poly(alkylacrylate) in Petroleum Wax," which is incorporated by reference. Copies are available from the addresses cited in this paragraph.

(d) Petroleum wax is used or intended for use as follows:

<table>
<thead>
<tr>
<th>Use</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>In chewing gum base, as a masticatory substance.</td>
<td>In an amount not to exceed good manufacturing practice.</td>
</tr>
<tr>
<td>On cheese and raw fruits and vegetables as a protective coating.</td>
<td>In accordance with § 173.340 of this chapter.</td>
</tr>
<tr>
<td>As a defoamer in food</td>
<td>Do.</td>
</tr>
<tr>
<td>As a component of microcapsules for spice-flavoring substances.</td>
<td>In accordance with § 172.230 of this chapter.</td>
</tr>
</tbody>
</table>

$[42$ FR 14491, Mar. 15, 1977, as amended at 59 FR 10986, Mar. 9, 1994]

§ 172.892 Food starch-modified.

Food starch-modified as described in this section may be safely used in food in accordance with the following conditions:
(a) Food starch may be acid-modified by treatment with hydrochloric acid or sulfuric acid or both.
(b) Food starch may be bleached by treatment with one or more of the following:

<table>
<thead>
<tr>
<th>Limitation in food</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>56 p.p.m</td>
<td>Coating.</td>
</tr>
<tr>
<td>do</td>
<td>Do.</td>
</tr>
<tr>
<td>2½ p.c.</td>
<td>Plasticizing material.</td>
</tr>
</tbody>
</table>

§ 172.892

(c) Food starch may be oxidized by treatment with chlorine, as sodium hypochlorite, not to exceed 0.0082 pound of chlorine per pound of dry starch.

(d) Food starch may be esterified by treatment with one of the following:

<table>
<thead>
<tr>
<th>Limitations</th>
<th>Acetyl groups in food starch-modified not to exceed 2.5 percent.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic anhydride</td>
<td>Do.</td>
</tr>
<tr>
<td>Adipic anhydride, not to exceed 0.12 percent, and acetic anhydride.</td>
<td>Do.</td>
</tr>
<tr>
<td>Phosphorus oxychloride, not to exceed 0.1 percent.</td>
<td>Do.</td>
</tr>
<tr>
<td>Phosphorus oxychloride, not to exceed 0.1 percent, followed by either acetic anhydride, not to exceed 8 percent, or vinyl acetate, not to exceed 7.5 percent.</td>
<td>Do.</td>
</tr>
<tr>
<td>Sodium trimetaphosphate</td>
<td>Do.</td>
</tr>
<tr>
<td>Sodium triphosphate and sodium trimetaphosphate.</td>
<td>Do.</td>
</tr>
<tr>
<td>Succinic anhydride, not to exceed 4 percent.</td>
<td>Do.</td>
</tr>
</tbody>
</table>

(e) Food starch may be etherified by treatment with one of the following:

<table>
<thead>
<tr>
<th>Limitations</th>
<th>Acetyl groups in food starch-modified not to exceed 2.5 percent.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acrolein, not to exceed 0.6 percent.</td>
<td>Do.</td>
</tr>
<tr>
<td>Epichlorohydrin, not to exceed 0.3 percent.</td>
<td>Do.</td>
</tr>
<tr>
<td>Epichlorohydrin, not to exceed 0.1 percent, and propylene oxide, not to exceed 10 percent.</td>
<td>Do.</td>
</tr>
<tr>
<td>Epichlorohydrin, not to exceed 0.1 percent, followed by propylene oxide, not to exceed 25 percent.</td>
<td>Do.</td>
</tr>
<tr>
<td>Propylene oxide, not to exceed 25 percent.</td>
<td>Do.</td>
</tr>
</tbody>
</table>

(f) Food starch may be esterified and etherified by treatment with one of the following:

<table>
<thead>
<tr>
<th>Limitations</th>
<th>Acetyl groups in food starch-modified not to exceed 2.5 percent.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acrolein, not to exceed 0.6 percent and vinyl acetate, not to exceed 7.5 percent.</td>
<td>Do.</td>
</tr>
<tr>
<td>Epichlorohydrin, not to exceed 0.3 percent, and acetic anhydride.</td>
<td>Do.</td>
</tr>
<tr>
<td>Epichlorohydrin, not to exceed 0.3 percent, and sucinic anhydride, not to exceed 4 percent.</td>
<td>Do.</td>
</tr>
<tr>
<td>Phosphorus oxychloride, not to exceed 0.1 percent, and propylene oxide, not to exceed 10 percent.</td>
<td>Do.</td>
</tr>
</tbody>
</table>

(g) Food starch may be modified by treatment with one of the following:

<table>
<thead>
<tr>
<th>Limitations</th>
<th>Acetyl groups in food starch-modified not to exceed 2.5 percent.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorine, as sodium hypochlorite, not to exceed 0.055 pound of chlorine per pound of dry starch.</td>
<td>Do.</td>
</tr>
<tr>
<td>Acetyls groups in food starch-modified not to exceed 0.04 percent, calculated as phosphorus.</td>
<td>Do.</td>
</tr>
<tr>
<td>Sodium hydroxide, not to exceed 1 percent.</td>
<td>Do.</td>
</tr>
</tbody>
</table>

(h) Food starch may be modified by a combination of the treatments prescribed by paragraphs (a), (b), and/or (i) of this section and any one of the treatments prescribed by paragraph (c), (d), (e), (f), or (g) of this section, subject to any limitations prescribed by the paragraphs named.
(1) Food starch may be modified by treatment with the following enzymes:

<table>
<thead>
<tr>
<th>Enzyme</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha-amylase (E.C. 3.2.1.1)</td>
<td>The enzyme must be generally recognized as safe or approved as a food additive for this purpose. The resulting nonsweet nutritive saccharide polymer has a dextrose equivalent of less than 20.</td>
</tr>
<tr>
<td>Beta-amylase (E.C. 3.2.1.2), Glucoamylase (E.C. 3.2.1.3), Isoamylase (E.C. 3.2.1.68), Pullulanase (E.C. 3.2.1.41)</td>
<td></td>
</tr>
</tbody>
</table>


§ 172.894 Modified cottonseed products intended for human consumption.

The food additive modified cottonseed products may be used for human consumption in accordance with the following prescribed conditions:

(a) The additive is derived from:
   (1) Decorticated, partially defatted, cooked, ground cottonseed kernels; or
   (2) Decorticated, ground cottonseed kernels, in a process that utilizes n-hexane as an extracting solvent in such a way that no more than 60 parts per million of n-hexane residues and less than 1 percent fat by weight remain in the finished product; or
   (3) Glandless cottonseed kernels roasted to attain a temperature of not less than 250 °F in the kernel for not less than 5 minutes for use as a snack food, or in baked goods, or in soft candy; or
   (4) Raw glandless cottonseed kernels may be used in hard candy where the kernel temperature during cooking will exceed 250 °F for not less than 5 minutes.

(b) The additive is prepared to meet the following specifications:
   (1) Free gossypol content not to exceed 450 parts per million.
   (2) It contains no added arsenic compound and therefore may not exceed a maximum natural background level of 0.2 part per million total arsenic, calculated as As.
   (3) To assure safe use of the additive, the label of the food additive container shall bear, in addition to other information required by the act, the name of the additive as follows:
      (1) The additive identified in paragraph (a)(1) of this section as “partially defatted, cooked cottonseed flour”.
      (2) The additive identified in paragraph (a)(2) of this section as “defatted cottonseed flour”.
      (3) The additive identified in paragraph (a)(3) of this section as “roasted glandless cottonseed kernels”.
      (4) The additive identified in paragraph (a)(4) of this section as “raw glandless cottonseed kernels for use in cooked hard candy”.

(d) The Food and Drug Administration and the Environmental Protection Agency have determined that glandless cottonseed kernels permitted for use by this section are a distinct commodity from glanded cottonseed.

§ 172.896 Dried yeasts.

Dried yeast (Saccharomyces cerevisiae and Saccharomyces fragilis) and dried torula yeast (Candida utilis) may be safely used in food provided the total folic acid content of the yeast does not exceed 0.04 milligram per gram of yeast (approximately 0.008 milligram of pteroylglutamic acid per gram of yeast).

§ 172.898 Bakers yeast glycan.

Bakers yeast glycan may be safely used in food in accordance with the following conditions:

(a) Bakers yeast glycan is the comminuted, washed, pasteurized, and dried cell walls of the yeast, Saccharomyces cerevisiae. It is composed principally of long chain carbohydrates, not less than 85 percent on a dry solids basis. The carbohydrate is composed of glycan and mannan units in approximately a 2:1 ratio.

(b) The additive meets the following specifications on a dry weight basis:
   (1) Free gossypol content not to exceed 450 parts per million.
   (2) It contains no added arsenic compound and therefore may not exceed a maximum natural background level of 0.2 part per million total arsenic, calculated as As.
   (3) To assure safe use of the additive, the label of the food additive container shall bear, in addition to other information required by the act, the name of the additive as follows:
      (1) Less than 10,000 organisms/gram by aerobic plate count.
      (2) Less than 10 yeasts and molds/gram.
(3) Negative for Salmonella, E. coli, coagulase positive Staphylococci, Clostridium perfringens, Clostridium botulinum, or any other recognized microbial pathogen or any harmful microbial toxin.

(d) The additive is used or intended for use in the following foods when standards of identity established under section 401 of the Act do not preclude such use:

<table>
<thead>
<tr>
<th>Use</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) In salad dressings as an emulsifier and emulsifier salt as defined in §170.3(o)(8) of this chapter, stabilizer and thickener as defined in §170.3(o)(28) of this chapter, or texturizer as defined in §170.3(o)(32) of this chapter.</td>
<td>Not to exceed a concentration of 5 percent of the finished salad dressing.</td>
</tr>
<tr>
<td>(2) In frozen dessert analogs as a stabilizer and thickener as defined in §170.3(o)(28) of this chapter, or texturizer as defined in §170.3(o)(32) of this chapter.</td>
<td>In an amount not to exceed good manufacturing practice.</td>
</tr>
<tr>
<td>(3) In sour cream analogs as a stabilizer and thickener as defined in §170.3(o)(28) of this chapter, or texturizer as defined in §170.3(o)(32) of this chapter.</td>
<td>Do.</td>
</tr>
<tr>
<td>(4) In cheese spread analogs as a stabilizer and thickener as defined in §170.3(o)(28) of this chapter, or texturizer as defined in §170.3(o)(32) of this chapter.</td>
<td>Do.</td>
</tr>
<tr>
<td>(5) In cheese-flavored and sour cream-flavored snack dips as a stabilizer and thickener as defined in §170.3(o)(28) of this chapter, or texturizer as defined in §170.3(o)(32) of this chapter.</td>
<td>Do.</td>
</tr>
</tbody>
</table>

(e) The label and labeling of the ingredient shall bear adequate directions to assure that use of the ingredient complies with this regulation.

(33 FR 14491, Mar. 15, 1977, as amended at 45 FR 58836, Sept. 5, 1980)

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

Subpart A—Polymer Substances and Polymer Adjuvants for Food Treatment

Sec.
173.5 Acrylate-acrylamide resins.
173.10 Modified polyacrylamide resin.
173.20 Ion-exchange membranes.
173.21 Perfluorinated ion exchange membranes.
173.25 Ion-exchange resins.
173.40 Molecular sieve resins.
173.45 Polymaleic acid and its sodium salt.
173.50 Polyvinylpyrrolidone.
173.55 Polyvinylpyrrolidone.
173.60 Dimethylamine-epichlorohydrin copolymer.
173.65 Divinylbenzene copolymer.
173.70 Chloromethylated amminated styrene-divinylbenzene resin.
173.73 Sodium polyacrylate.
173.75 Sorbitan monooleate.

Subpart B—Enzyme Preparations and Microorganisms

173.110 Amyloglucosidase derived from Rhizopus niveus.
173.115 Alpha-acetolactate decarboxylase (α-ALDC) enzyme preparation derived from a recombinant Bacillus subtilis.
173.120 Carbohydrase and cellulase derived from Aspergillus niger.
173.130 Carbohydrase derived from Rhizopus oryzae.
173.135 Catalase derived from Micrococcus lysodeikticus.
173.140 Esterase-lipase derived from Mucor miehei.
173.145 Alpha-Galactosidase derived from Mortierella vinacea var. raffinoseutilizer.
173.150 Milk-clotting enzymes, microbial.
173.160 Candida guilliermondii.
173.165 Candida lipolytica.
173.170 Aminoglycoside 3′-phosphotransferase II.

Subpart C—Solvents, Lubricants, Release Agents and Related Substances

173.210 Acetone.
173.220 1,3-Butylene glycol.
173.228 Ethyl acetate.
173.230 Ethylene dichloride.
173.240 Isopropyl alcohol.
173.250 Methyl alcohol residues.
173.255 Methylene chloride.
173.270 Hexane.
173.275 Hydrogenated sperm oil.
173.280 Solvent extraction process for citric acid.
173.290 Trichloroethylene.

Subpart D—Specific Usage Additives

173.300 Chlorine dioxide.
173.310 Boiler water additives.
173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables.
173.320 Chemicals for controlling microorganisms in cane-sugar and beet-sugar mills.
173.322 Chemicals used in delinting cottonseed.
173.325 Acidified sodium chlorite solutions.
173.340 Defoaming agents.
173.342 Chlorofluorocarbon 113 and perfluorohexane.