Food and Drug Administration, HHS

§ 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) Any substance intended for use in or on food is of appropriate food grade and is prepared and handled as a food ingredient.

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

172.571 Calcium lignosulfonate.
172.572 Calcium lactobionate.
172.573 Epoxidized soybean oil.
172.574 Gibberellic acid and its potassium salt.
172.575 Potassium bromate.
172.576 Glycerol ester of rosin.
172.577 Methacrylic acid-divinylbenzene copolymer.
172.578 Acacia (gum arabic).
172.580 Acesulfame potassium.
172.582 Acetone peroxides.
172.584 Aspartame.
172.586 Azodicarbonamide.
172.589 Copolymer condensates of ethylene oxide and propylene oxide.
172.590 Curdlan.
172.591 Dioctyl sodium sulfosuccinate.
172.592 Glyceryl tristearate.
172.593 Hydroxylated lecithin.
172.595 Methyl glucoside-coconut oil ester.
172.597 Oxystearin.
172.598 Polyethylene glycol (mean molecular weight 200–9,500).
172.599 Sodium lauryl sulfate.
172.601 Sodium stearoyl fumarate.
172.602 Acetylated monoglycerides.
172.603 Neotame.
172.604 Succinylated monoglycerides.
172.605 Sucrose fatty acid esters.
172.606 Sodium stearoyl lactylate.
172.607 Lactic acid esters of fatty acids.
172.608 Propylene glycol mono- and diesters of fats and fatty acids.
172.609 Pectin.
172.610 Cocoa butter substitute from coconut oil, palm kernel oil, or both oils.
172.612 Oleic acid derived from tall oil fatty acids.
172.613 Salts of fatty acids.
172.614 Synthetic fatty acids.
172.615 Synthetic glycerin produced by the hydrogenolysis of carbohydrates.
172.616 Olestra.
172.617 Ethyl cellulose.
172.618 Sucrose oligoesters.
172.619 Hydroxypropyl cellulose.
172.620 Methyl ethyl cellulose.
172.621 Hydroxypropyl methylcellulose.
172.622 Sodium stearoyl lactylate.
172.624 Stearyl monoglyceridyl citrate.
172.625 Succistearin (stearoyl propylene glycol hydrogen succinate).
172.626 Glycerides and polyglycides of hydrogenated vegetable oils.
172.627 Ethylene oxide polymer.
172.628 Methacrylic acid-divinylbenzene copolymer.
172.629 Sodium unilaurate.
172.630 Sodium polyphosphate.
172.631 Sodium lauryl sulfate.
172.632 Sodium tripolyphosphate.
172.633 Sodium dodecyl sulfate.
172.634 Sodium laurel sulfonate.
172.635 Sodium benzoate.
172.636 Propylene glycol mono- and diesters of fats and fatty acids.
172.637 Sodium stearoyl-2-lactylate.
172.638 Sodium stearyl fumarate.
172.639 Sodium stearoyl lactylate.
172.640 Sodium stearoyl-2-lactylate.
172.641 Sodium lactate.
172.642 Sodium propionate.
172.643 Sodium starch octenylsuccinate.
172.644 Sodium stearoyl-2-lactylate.
172.645 Sodium stearoyl lactylate.
172.646 Sodium stearoyl lactylate.
172.647 Lactic acid esters of fatty acids.
172.648 Propylene glycol mono- and diesters of fats and fatty acids.
172.649 Pectin.
172.650 Propylene glycol alginate.
172.651 Pectin.
172.652 Propylene glycol alginate.
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172.661 Propylene glycol alginate.
§ 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 diethylenbenzene, 4-(1,1-dimethyl-ethyl)phenol, 4-methoxyphenol, 4,4’-(1-methylallylidene)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.

(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>11,000</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>132</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>