Food and Drug Administration, HHS

without being considered to be reirradiated.

[60 FR 50099, Sept. 28, 1995]

PART 582—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Subpart A—General Provisions

Sec

- 582.1 Substances that are generally recognized as safe.
- 582.10 Spices and other natural seasonings and flavorings.
- 582.20 Essential oils, oleoresins (solventfree), and natural extractives (including distillates)
- 582.30 Natural substances used in conjunction with spices and other natural seasonings and flavorings.
- 582.40 Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings.
- 582.50 Certain other spices, seasonings, essential oils, oleoresins, and natural extracts.
- 582.60 Synthetic flavoring substances and adjuvants.
- 582.80 Trace minerals added to animal feeds.
- 582.99 Adjuvants for pesticide chemicals.

Subpart B—General Purpose Food Additives

- 582.1005 Acetic acid. 582.1009
- Adipic acid.
- 582.1033 Citric acid.
- 582.1057 Hydrochloric acid.
- 582.1061 Lactic acid.
- 582.1069 Malic acid.
- 582.1073 Phosphoric acid.
- 582.1077 Potassium acid tartrate. 582.1087
- Sodium acid pyrophosphate.
- 582.1091 Succinic acid. 582.1095
- Sulfuric acid 582.1099 Tartaric acid
- 582.1125 Aluminum sulfate.
- 582.1127 Aluminum ammonium sulfate.
- 582,1129 Aluminum potassium sulfate.
- 582.1131 Aluminum sodium sulfate.
- 582.1135 Ammonium bicarbonate.
- 582.1137 Ammonium carbonate.
- 582.1139 Ammonium hydroxide.
- 582.1141 Ammonium phosphate.
- 582.1143 Ammonium sulfate.
- 582.1155 Bentonite.
- 582.1165 Butane.
- 582.1191 Calcium carbonate.
- 582,1193 Calcium chloride.
- 582 1195 Calcium citrate
- 582,1199 Calcium gluconate.
- 582,1205 Calcium hydroxide.
- 582 1207 Calcium lactate.
- 582.1210 Calcium oxide.
- 582.1217 Calcium phosphate.

582 1235 Caramel 582,1240 Carbon dioxide.

- 582 1275 Dextrans
- 582,1320 Glycerin.
- Glyceryl monostearate. 582.1324

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- 582,1355 Helium.
- 582.1366 Hydrogen peroxide.
- 582.1400 Lecithin.
- 582,1425 Magnesium carbonate.
- 582 1428 Magnesium hydroxide.
- Magnesium oxide. 582.1431
- 582 1480 Methylcellulose. 582.1500
- Monoammonium glutamate.
- 582,1516 Monopotassium glutamate.
- 582.1540 Nitrogen.
- 582.1585 Papain.
- 582.1613 Potassium bicarbonate.
- 582.1619 Potassium carbonate.
- 582,1625 Potassium citrate.
- 582.1631 Potassium hydroxide.
- 582.1643 Potassium sulfate.
- 582.1655Propane.
- 582.1666 Propylene glycol.
- 582.1685 Rennet.
- 582.1711 Silica aerogel.
- 582.1721 Sodium acetate.
- 582.1736 Sodium bicarbonate.
- 582.1742 Sodium carbonate.
- 582.1745 Sodium carboxymethylcellulose.
- 582.1748 Sodium caseinate.
- 582.1751 Sodium citrate.
- 582.1763 Sodium hydroxide.
- 582.1775 Sodium pectinate. 582.1778 Sodium phosphate.
- 582.1781 Sodium aluminum phosphate. 582.1792 Sodium sesquicarbonate.
- 582.1804 Sodium potassium tartrate.
- 582.1810 Sodium tripolyphosphate.
- 582.1901 Triacetin.
- 582.1973 Beeswax.
- Bleached beeswax. 582,1975
- 582.1978 Carnauba wax.

Subpart C—Anticaking Agents

- 582.2122 Aluminum calcium silicate.
- 582.2227 Calcium silicate.
- 582.2437 Magnesium silicate
- 582.2727 Sodium aluminosilicate. 582.2729 Hydrated sodium calcium alumino-
- silicate.
- 582.2906 Tricalcium silicate.

Subpart D—Chemical Preservatives

Thiodipropionic acid.

Butylated hydroxyanisole.

Butylated hydroxytoluene.

Ascorbyl palmitate.

Calcium ascorbate.

Calcium propionate.

- 582.3013 Ascorbic acid.
- 582.3021 Benzoic acid.
- 582.3041 Erythorbic acid.

582.3225 Calcium sorbate.

- 582.3081 Propionic acid.
- 582.3089 Sorbic acid.

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- 582 3280 Dilauryl thiodipropionate.
- 582.3336 Gum guaiac. 582.3490
- Methylparaben. 582.3616 Potassium bisulfite.
- 582.3637 Potassium metabisulfite.
- 582.3640 Potassium sorbate.
- 582.3660
- Propyl gallate. 582.3670
- Propylparaben.
- 582.3731 Sodium ascorbate.
- 582.3733 Sodium benzoate
- 582.3739 Sodium bisulfite.
- 582.3766 Sodium metabisulfite.
- 582.3784 Sodium propionate.
- 582.3795 Sodium sorbate.
- 582.3798 Sodium sulfite.
- 582.3845 Stannous chloride.
- 582.3862 Sulfur dioxide.
- 582.3890 Tocopherols.

Subpart E—Emulsifying Agents

- 582.4101 Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.
- 582.4505 Mono- and diglycerides of edible fats or oils, or edible fat-forming acids.
- 582.4521 Monosodium phosphate derivatives of mono- and diglycerides of edible fats
- or oils, or edible fat-forming fatty acids. 582.4666 Propylene glycol.

Subpart F—Nutrients and/or Dietary Supplements

- 582.5013 Ascorbic acid.
- 582,5017 Aspartic acid.
- Aminoacetic acid.
- 582,5049
- 582.5065 Linoleic acid.
- 582.5118 Alanine.
- 582.5145 Arginine.
- 582.5159 Biotin.
- 582.5191 Calcium carbonate.
- 582.5195 Calcium citrate.
- 582.5201 Calcium glycerophosphate.
- 582.5210 Calcium oxide.
- 582.5212 Calcium pantothenate.
- 582.5217 Calcium phosphate.
- 582.5223 Calcium pyrophosphate.
- 582.5230 Calcium sulfate.
- 582.5245 Carotene.
- 582.5250 Choline bitartrate.
- Choline chloride. 582.5252 Copper gluconate.
- 582.5260 582.5271 Cysteine.
- 582.5273
- Cystine.
- 582.5301 Ferric phosphate.
- Ferric pyrophosphate. 582.5304 582.5306
- Ferric sodium pyrophosphate. Ferrous gluconate. Ferrous lactate. 582.5308
- 582.5311
- 582.5315 Ferrous sulfate.
- 582.5361 Histidine
- 582.5370 Inositol.
- 582.5375 Iron reduced.
- 582 5381 Isoleucine
- 582,5406 Leucine.
- 582.5411 Lysine.

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- 582 5431 Magnesium oxide.
- 582.5434 Magnesium phosphate. 582.5443
- Magnesium sulfate. 582.5446 Manganese chloride.
- 582.5449 Manganese citrate.
- 582.5452 Manganese gluconate.
- 582.5455
- Manganese glycerophosphate. Manganese hypophosphite. 582.5458
- 582.5461 Manganese sulfate.
- 582.5464 Manganous oxide.
- 582.5470 Mannitol. 582.5475
- Methionine.
- 582.5477 Methionine hydroxy analog and its calcium salts.
- 582.5530 Niacin. 582.5535 Niacinamide.
- 582.5580
- D-Pantothenyl alcohol.
- 582.5590 Phenylalanine.
- 582.5622 Potassium chloride.
- Potassium glycerophosphate. Potassium iodide. 582.5628
- 582.5634
- 582.5650 Proline.
- Pvridoxine hydrochloride. 582.5676
- 582.5695 Riboflavin.
- 582.5697 Riboflavin-5-phosphate.
- 582.5701 Serine.
- 582.5772 Sodium pantothenate.
- 582.5778 Sodium phosphate.
- 582.5835 Sorbitol.
- 582.5875 Thiamine hydrochloride.
- 582.5878 Thiamine mononitrate.
- 582.5881 Threonine. 582.5890 Tocopherols.
- 582.5892 a-Tocopherol acetate.
- 582.5915 Tryptophane.
- 582.5920
- Tyrosine. Valine. 582.5925
- 582.5930 Vitamin A.

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- 582.5933 Vitamin A acetate.
- 582 5936 Vitamin A palmitate. Vitamin B₁₂. Vitamin D₂.

Vitamin D₃

Zinc oxide.

Zinc chloride

Zinc gluconate.

Zinc stearate.

Subpart G—Sequestrants

Calcium gluconate. Calcium hexametaphosphate.

Monobasic calcium phosphate.

Sodium acid phosphate.

Zinc sulfate.

Citric acid.

Tartaric acid.

Calcium acetate.

Calcium chloride.

Calcium citrate.

Calcium phytate.

Isopropyl citrate.

Potassium citrate.

Dipotassium phosphate.

Monoisopropyl citrate.

Disodium phosphate.

Calcium diacetate.

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- Sodium citrate 582 6751
- 582 6754 Sodium diacetate.
- 582 6757 Sodium gluconate. 582.6760
- Sodium hexametaphosphate. 582.6769 Sodium metaphosphate.
- 582.6778 Sodium phosphate.
- 582.6787 Sodium pyrophosphate.
- 582.6789 Tetra sodium pyrophosphate.
- 582,6801 Sodium tartrate.
- 582,6804 Sodium potassium tartrate.
- 582 6807 Sodium thiosulfate.
- 582.6810 Sodium tripolyphosphate.
- 582.6851 Stearyl citrate.

Subpart H—Stabilizers

- 582.7115 Agar-agar.
- 582.7133 Ammonium alginate.
- 582.7187 Calcium alginate.
- 582.7255 Chondrus extract.
- 582.7330 Gum arabic.
- 582.7333 Gum ghatti.
- 582.7339 Guar gum.
- 582.7343 Locust bean gum. 582.7349
- Sterculia gum. 582.7351
- Gum tragacanth.
- 582.7610 Potassium alginate. 582.7724 Sodium alginate.

AUTHORITY: 21 U.S.C. 321, 342, 348, 371.

SOURCE: 41 FR 38657, Sept. 10, 1976, unless otherwise noted.

Subpart A—General Provisions

§582.1 Substances that are generally recognized as safe.

(a) It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, sugar, vinegar, baking powder, and monosodium glutamate as safe for their intended use. The lists in subparts B through H of this part include additional substances that, when used for the purposes indicated, in accordance with good manufacturing or feeding practice, are regarded by the Commissioner as generally recognized as safe for such uses.

(b) For the purposes of this section, good manufacturing or feeding practice shall be defined to include the following restrictions:

(1) The quantity of a substance added to animal food does not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food; and

(2) The quantity of a substance that becomes a component of animal food as a result of its use in the manufacturing, processing, or packaging of food, and which is not intended to accomplish any physical or other technical effect in the food itself, shall be reduced to the extent reasonably possible.

(3) The substance is of appropriate grade and is prepared and handled as a food ingredient. Upon request the Commissioner will offer an opinion, based on specifications and intended use, as to whether or not a particular grade or lot of the substance is of suitable purity for use in food and would generally be regarded as safe for the purpose intended, by experts qualified to evaluate its safety.

(c) The inclusion of substances in the list of nutrients does not constitute a finding on the part of the Department that the substance is useful as a supplement to the diet for animals.

(d) Substances that are generally recognized as safe for their intended use within the meaning of section 409 of the Act are listed in subparts B through H of this part. When the status of a substance has been reevaluated and affirmed as GRAS or deleted from subparts B through H of this part, an appropriate explanation will be noted, e.g., "affirmed as GRAS," "food additive regulation," "interim food additive regulation," or "prohibited from use in food," with a reference to the appropriate new regulation. Such notation will apply only to the specific use covered by the review, e.g., direct animal food use and/or indirect animal food use and/or animal feed use and will not affect its status for other uses not specified in the referenced regulation, pending a specific review of such other uses.

§582.10 Spices and other natural seasonings and flavorings.

Spices and other natural seasonings and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows: