

Food and Drug Administration, HHS

§ 584.700

used in accordance with good manufacturing or feeding practice.

§ 582.7339 Guar gum.

(a) *Product.* Guar gum.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7343 Locust bean gum.

(a) *Product.* Locust (carob) bean gum.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7349 Sterculia gum.

(a) *Product.* Sterculia gum (karaya gum).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7351 Gum tragacanth.

(a) *Product.* Tragacanth (gum tragacanth).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7610 Potassium alginate.

(a) *Product.* Potassium alginate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

§ 582.7724 Sodium alginate.

(a) *Product.* Sodium alginate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing or feeding practice.

PART 584—FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE IN FEED AND DRINKING WATER OF ANIMALS

Subpart A [Reserved]

Subpart B—Listing of Specific Substances Affirmed as GRAS

Sec.

584.200 Ethyl alcohol containing ethyl acetate.

584.700 Hydrophobic silicas.

584.725 25-Hydroxyvitamin D₃.

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

Subpart A [Reserved]

Subpart B—Listing of Specific Substances Affirmed as GRAS

§ 584.200 Ethyl alcohol containing ethyl acetate.

The feed additive ethyl alcohol containing ethyl acetate meets the requirement of 27 CFR 21.62, being not less than 92.5 percent ethyl alcohol, each 100 gallons having had added the equivalent of 4.25 gallons of 100 percent ethyl acetate. It is used in accordance with good feeding practices in ruminant feed supplements as a source of added energy.

[46 FR 52333, Oct. 27, 1981, as amended at 72 FR 41620, July 31, 2007]

§ 584.700 Hydrophobic silicas.

(a) *Product.* Amorphous fumed hydrophobic silica or precipitated hydrophobic silica (CAS Reg. No. 68611-0944-099, silane, dichlorodimethyl-, reaction products with silica).

(b) *Conditions of use.* An anticaking/free-flow agent in vitamin preparations for animal feed.

(c) *Limitations.* Not to exceed 5 percent in the vitamin preparation. It shall be used in accordance with good manufacturing or feeding practices. It must be of purity suitable for intended use, and it must comply with the following specifications:

(i) Amorphous fumed hydrophobic silica: Not less than 99.0 percent silicon dioxide after ignition. Not more than 3 ppm arsenic. Not more than 0.003 percent heavy metals (as lead). Not more than 10 ppm lead. Not more than 2.5 percent loss on drying. Not more than 2 percent loss on ignition after drying. Not more than 1 percent insoluble substances. Not more than 50 parts per million dichlorodimethylsilane.

§ 584.725

(ii) Precipitated hydrophobic silica: Not less than 94.0 percent silicon dioxide after ignition. Not more than 3 ppm arsenic. Not more than 0.003 percent heavy metals (as lead). Not more than 10 ppm lead. Not more than 7 percent loss on drying. Not more than 8.5 percent loss on ignition after drying. Not more than 5 percent soluble ionizable salts (as sodium sulfate). Not more than 1 percent insoluble substances. Not more than 50 parts per million dichlorodimethylsilane.

[61 FR 43453, Aug. 23, 1996]

§ 584.725 25-Hydroxyvitamin D₃.

(a) *Product.* 25-Hydroxyvitamin D₃ (9,10-secocholesta-5,7,10(19)-triene-3β, 25-diol).

(b) *Conditions of use.* This substance is generally recognized as safe as a source of vitamin D₃ activity in feed or drinking water of broiler chickens when used in accordance with the limitations in paragraph (c) of this section.

(c) *Limitations.* (1) Not to exceed 69 parts per billion (ppb) in feed or 34.5 ppb in drinking water. It shall be used in accordance with good manufacturing and feeding practices.

(2) The product must comply with the following specifications:

(i) Not less than 94.0 percent 25-hydroxyvitamin D₃.

(ii) Not more than 1 percent of any individual sterol.

(iii) Not more than 5 percent water.

(iv) Not more than 20 parts per million (ppm) lead.

(v) Not more than 20 ppm aluminum.

(vi) Not more than 1.0 percent solvents and non-detectable levels of 2'. 4'. 5'. 7'-tetraiodofluorescein.

(3) Product labeling shall bear the following:

(i) A statement to indicate that the maximum use level of 25-hydroxyvitamin D₃ must not exceed 69 ppb in feed or 34.5 ppb in drinking water.

(ii) Adequate use directions to ensure that 25-hydroxyvitamin D₃ (and all pre-mixes) is uniformly blended throughout the feed or drinking water.

(iii) An expiration date on all premix labeling.

(iv) A statement on all premix labeling (feed and drinking water forms) that 25-hydroxyvitamin D₃ should not

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be used simultaneously in both feed and water.

[72 FR 12564, Mar. 16, 2007]

PART 589—SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

Subpart A—General Provisions

Sec.

589.1 Substances prohibited from use in animal food or feed.

Subpart B—Listing of Specific Substances Prohibited From Use in Animal Food or Feed

589.1000 Gentian violet.

589.1001 Propylene glycol in or on cat food.

589.2000 Animal proteins prohibited in ruminant feed.

589.2001 Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy.

AUTHORITY: 21 U.S.C. 321, 342, 343, 348, 371.

Subpart A—General Provisions

§ 589.1 Substances prohibited from use in animal food or feed.

(a) The substances listed in this part have been prohibited from use in animal food or feed by the Food and Drug Administration because of a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in such food or feed. Use of any of these substances in violation of this part causes the animal food or feed involved to be adulterated and in violation of the Act.

(b) This part includes only a partial list of substances prohibited from use in animal food or feed; it is for easy reference purposes and is not a complete list of substances that may not lawfully be used in such animal food or feed. No substance may be used in animal food or feed unless it meets all applicable requirements of the Act.

(c) The Food and Drug Administration either on its own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish, amend, or repeal a regulation under this part on the