

**§ 584.725**

**21 CFR Ch. I (4–1–08 Edition)**

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.

(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 D<sub>3</sub>.**

(a) *Product.* 25-Hydroxyvitamin D<sub>3</sub> (9,10-secosteroid-5,7,10(19)-triene-3β, 25-diol).

(b) *Conditions of use.* This substance is generally recognized as safe as a source of vitamin D<sub>3</sub> 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 D<sub>3</sub>.

(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 D<sub>3</sub> must not exceed 69 ppb in feed or 34.5 ppb in drinking water.

(ii) Adequate use directions to ensure that 25-hydroxyvitamin D<sub>3</sub> (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 D<sub>3</sub> should not 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**

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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 basis of new scientific evaluation or information. Any such petition shall include an adequate scientific basis to support the petition, shall be the form set forth in §571.1 of this chapter, and will be published in the FEDERAL REGISTER for comment if it contains reasonable ground.

[45 FR 28319, Apr. 29, 1980]

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

#### § 589.1000 Gentian violet.

The Food and Drug Administration has determined that gentian violet has not been shown by adequate scientific data to be safe for use in animal feed. Use of gentian violet in animal feed causes the feed to be adulterated and in violation of the Federal Food, Drug, and Cosmetic Act (the act), in the absence of a regulation providing for its safe use as a food additive under section 409 of the act, unless it is subject to an effective notice of claimed investigational exemption for a food additive under §570.17 of this chapter, or unless the substance is intended for use as a new animal drug and is subject to an approved application under section 512 of the act, or an index listing under section 572 of the act, or an effective notice of claimed investigational exemption for a new animal drug under part 511 of this chapter or §516.125 of this chapter.

[72 FR 69131, Dec. 6, 2007]

#### § 589.1001 Propylene glycol in or on cat food.

The Food and Drug Administration has determined that propylene glycol in or on cat food has not been shown by adequate scientific data to be safe for use. Use of propylene glycol in or on cat food causes the feed to be adulter-

ated and in violation of the Federal Food, Drug, and Cosmetic Act (the act), in the absence of a regulation providing for its safe use as a food additive under section 409 of the act, unless it is subject to an effective notice of claimed investigational exemption for a food additive under §570.17 of this chapter, or unless the substance is intended for use as a new animal drug and is subject to an approved application under section 512 of the act or an effective notice of claimed investigational exemption for a new animal drug under part 511 of this chapter.

[61 FR 19544, May 2, 1996]

#### § 589.2000 Animal proteins prohibited in ruminant feed.

(a) *Definitions*—(1) *Protein derived from mammalian tissues* means any protein-containing portion of mammalian animals, excluding: Blood and blood products; gelatin; inspected meat products which have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings); milk products (milk and milk proteins); and any product whose only mammalian protein consists entirely of porcine or equine protein.

(2) *Renderer* means any firm or individual that processes slaughter byproducts, animals unfit for human consumption, or meat scraps. The term includes persons who collect such materials and subject them to minimal processing, or distribute them to firms other than renderers (as defined here) whose intended use for the products may include animal feed. The term includes renderers that also blend animal protein products.

(3) *Blender* means any firm or individual which obtains processed animal protein from more than one source or from more than one species, and subsequently mixes (blends) or redistributes an animal protein product.

(4) *Feed manufacturer* includes manufacturers of complete and intermediate feeds intended for animals, and includes on-farm in addition to off-farm feed manufacturing and mixing operations.

(5) *Nonmammalian protein* includes proteins from nonmammalian animals.