

**§ 573.940**

**21 CFR Ch. I (4–1–13 Edition)**

Inventory, production, and distribution records must provide a complete and accurate history of product production. Production controls must assure products to be what they are purported and labeled. Production controls shall include analysis sufficient to adequately monitor quality.

(f) The label or labeling of any selenium premix shall bear adequate directions and cautions for use including this statement: "Caution: Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted."

(g) The additive is orally administered to beef and dairy cattle as an osmotically controlled, constant release bolus containing sodium selenite. Each bolus contains 360 milligrams of selenium as sodium selenite, and delivers 3 milligrams of selenium per day for 120 days. To ensure safe use of the additive:

(1) The osmotically controlled, constant release bolus is for use only in beef and dairy cattle more than 3 months of age or over 200 pounds body weight.

(2) Only one bolus containing 360 milligrams of selenium as sodium selenite is administered orally to each animal in 120 days.

(3) The labeling shall bear the following: "This bolus delivers the maximum daily allowable amount of selenium and shall be the sole source of supplementation. Do not use in areas containing excess selenium. Do not rebolus within 4 months."

(h) Selenium yeast is a dried, non-viable yeast (*Saccharomyces cerevisiae*) cultivated in a fed-batch fermentation which provides incremental amounts of cane molasses and selenium salts in a manner which minimizes the detrimental effects of selenium salts on the growth rate of the yeast and allows for optimal incorporation of inorganic selenium into cellular organic material. Residual inorganic selenium is eliminated in a rigorous washing process and must not exceed 2 percent of the total selenium content in the final selenium yeast product.

(1) Selenium, as selenium yeast, is added to feed as follows:

(i) In complete feed for chickens, turkeys, swine, beef cattle, and dairy cat-

tle at a level not to exceed 0.3 part per million.

(ii) In feed supplements for limit feeding for beef cattle at a level not to exceed an intake of 3 milligrams per head per day.

(iii) In salt-mineral mixtures for free-choice feeding for beef cattle up to 120 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 3 milligrams per head per day.

(2) Guaranteed organic selenium content from selenium yeast must be declared on the selenium yeast product label.

(3) The additive, as selenium yeast, shall be incorporated into feed as follows:

(i) It shall be incorporated into each ton of complete feed by adding no less than 1 pound of a premix containing no more than 272.4 milligrams of added selenium per pound.

(ii) It shall be incorporated into each ton of salt-mineral mixture for beef cattle from a premix containing no more than 4.5 grams of added selenium per pound.

(4) Usage of this additive must conform to the requirements of paragraphs (e) and (f) of this section.

[52 FR 10888, Apr. 6, 1987; 52 FR 21001, June 4, 1987, as amended at 54 FR 14215, Apr. 10, 1989; 54 FR 15874, Apr. 19, 1989; 60 FR 53703, Oct. 17, 1995; 65 FR 35824, June 6, 2000; 65 FR 53167, Sept. 1, 2000; 67 FR 46851, July 17, 2002; 68 FR 52340, Sept. 3, 2003; 72 FR 39561, July 19, 2007]

EFFECTIVE DATE NOTE: At 58 FR 47973, Sept. 13, 1993, the amendments to § 573.920 that were published at 52 FR 10887, Apr. 6, 1987; 52 FR 21001, June 4, 1987; and 54 FR 14214, Apr. 10, 1989 were stayed until further notice. At 59 FR 45973, Sept. 6, 1994, the stay was confirmed.

**§ 573.940 Silicon dioxide.**

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

(a) The food additive is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect.

(b) It is used or intended for use in feed components as an anticaking agent, and/or grinding aid, as follows:

Feed component	Limitations (percent)
BHT (butylated hydroxytoluene) .....	2
Methionine hydroxy analog and its calcium salts .....	1
Piperazine, piperazine salts .....	0.8
Sodium propionate .....	1
Urea .....	1
Vitamins .....	3

(c) It is used in feed as an anticaking agent in an amount not to exceed that reasonably required to accomplish its intended effect and in no case in an amount to exceed 2 percent by weight of the finished feed.

**§ 573.960 Sorbitan monostearate.**

The food additive sorbitan monostearate may be safely used alone or in combination with polysorbate 60 as an emulsifier in mineral premixes and dietary supplements for animal feeds.

**§ 573.980 Taurine.**

The food additive taurine (2-aminoethanesulfonic acid) may be safely used in feed in accordance with the following prescribed conditions:

- (a) It is used as a nutritional supplement in the feed of growing chickens.
- (b) It is added to complete feeds so that the total taurine content does not exceed 0.054 percent of the feed.
- (c) To assure safe use of the additive, the label and labeling shall bear in addition to the other information required by the Act:
  - (1) The name of the additive.
  - (2) The quantity of the additive contained therein.
  - (3) Adequate directions for use.

**§ 573.1000 Verxite.**

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

- (a) The additive is a magnesium-aluminum-iron silicate conforming to one of the following:
  - (1)(i) Verxite granules: The additive contains a minimum of 98 percent of hydrobiotite; it is thermally expanded and has a bulk density of from 5 to 9 pounds per cubic foot.
  - (ii) It is used or intended for use:
    - (a) In poultry feed at a level not to exceed 5 percent of the weight of the finished feed as a nonnutritive bulking

agent for restricting calorie intake in pullet replacement feeds.

(b) As an anticaking or blending agent, pelleting aid, or nonnutritive carrier for the incorporation of nutrients in poultry, swine, dog, or ruminant feeds, in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 1.5 percent of the dog feed or 5 percent of the final feed for other animals.

(2)(i) Verxite flakes: The additive contains a minimum of 98 percent of hydrobiotite; it has a bulk density of from 20 to 30 pounds per cubic foot.

(ii) It is used or intended for use as an anticaking or blending agent in ruminant feeds in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 1 percent by weight of the final feed for ruminants.

(3)(i) Verxite grits: The additive contains a minimum of 80 percent of hydrobiotite; it has a bulk density of from 40 to 50 pounds per cubic foot.

(ii) It is used or intended for use as a partial roughage replacement in ruminant feeds in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 1 percent by weight of the final feed.

(b) To assure safe use of the additive, the label of any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall bear, in addition to the other information required by the Act, the name of the additive (verxite granules, verxite flakes, or verxite grits), adequate directions for use, and, when the additive is present in excess of 1 percent, a statement of the quantity of the additive contained therein and the term "nonnutritive" in juxtaposition therewith.

**§ 573.1010 Xanthan gum.**

The food additive xanthan gum may be safely used in animal feed as follows:

- (a) The food additive is xanthan gum as defined in § 172.695 of this chapter and meets all of the specifications thereof.
  - (b) It is used or intended for use as a stabilizer, emulsifier, thickener, suspending agent, or bodying agent in animal feed as follows: