

§ 573.920

21 CFR Ch. I (4–1–10 Edition)

volatile fatty acids and shall conform to the following specifications:

(1) Ammonium salts:

Components	Amount
Ammonium salts of mixed 5-carbon acids (as identified in paragraph (a) of this section).	48 to 54 percent.
Ammonium salt of isobutyric acid	22 to 26 percent.
Water	28 percent maximum.
Ammonia	0.3 percent maximum.
Arsenic	3 parts per million maximum.
Heavy metals such as lead	10 parts per million maximum.

(2) Calcium salts:

Components	Amount
Calcium salts of mixed 5-carbon acids (as identified in paragraph (a) of this section).	58 to 72 percent.
Calcium salt of isobutyric acid	26 to 34 percent.
Calcium hydroxide	3 percent maximum.
Water	14 percent maximum.
Arsenic	3 parts per million maximum.
Heavy metals such as lead	10 parts per million maximum.

(c) *Use.* The additive is used or intended for use as a source of energy in dairy cattle feed.

(d) *Labeling.* The label and labeling of the additive in any feed, feed supplement, feed concentrate, feed premix, or liquid feed supplement prepared therefrom shall bear, in addition to other information required by the act, the following:

(1) The name of the additive.

(2) Adequate directions for use, including statements expressing maximum use levels. For ammonium salts of volatile fatty acids, the statements: “Not to exceed 160 grams per head per day thoroughly mixed in dairy cattle feed as a source of energy.” For calcium salts of volatile fatty acids, the statement: “Not to exceed 135 grams per head per day thoroughly mixed in dairy cattle feed as a source of energy.”

[49 FR 45125, Nov. 15, 1984; 50 FR 8606, Mar. 4, 1985, as amended at 70 FR 13100, Mar. 18, 2005]

§ 573.920 Selenium.

(a) Public Law 103–354 enacted October 13, 1994 (the 1994 Act), states that FDA shall not implement or enforce the final rule issued on September 13, 1993 (58 FR 47962), in which FDA stayed the 1987 amendments and any modifica-

tion of such rule issued after enactment of the 1994 Act; unless the Commissioner of Food and Drugs makes a determination that:

(1) Selenium additives are not essential at levels authorized in the absence of such final rule, to maintain animal nutrition and protect animal health;

(2) selenium at such levels is not safe to the animals consuming the additive;

(3) selenium at such levels is not safe to individuals consuming edible portions of animals that receive the additive;

(4) selenium at such levels does not achieve its intended effect of promoting normal growth and reproduction of livestock and poultry; and

(5) the manufacture and use of selenium at such levels cannot reasonably be controlled by adherence to current good manufacturing practice requirements.

(6) Paragraphs (b) through (g) of this section provide the currently acceptable levels of selenium supplementation.

(b) The food additive selenium is a nutrient administered in animal feed as sodium selenite or sodium selenate or in a controlled-release sodium selenite bolus, as provided in paragraphs (f) and (g) of this section, or as selenium yeast, as provided in paragraph (h) of this section.

(c) It is added to feed as follows:

(1) In complete feed for chickens, swine, turkeys, sheep, cattle, and ducks at a level not to exceed 0.3 part per million.

(2) In feed supplements for limit feeding as follows:

(i) *Sheep:* At a level not to exceed an intake of 0.7 milligram per head per day.

(ii) *Beef cattle:* At a level not to exceed an intake of 3 milligrams per head per day.

(3) In salt-mineral mixtures for free-choice feeding as follows:

(i) *Sheep:* Up to 90 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 0.7 milligram per head per day.

(ii) *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.

(d) The additive shall be incorporated into feed as follows:

(1) 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.

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

(e) The premix manufacturer shall follow good manufacturing practices in the production of selenium premixes. 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 reboilus 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 cattle 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.