

§ 573.880

21 CFR Ch. I (4–1–13 Edition)

for beef cattle and dairy cattle and replacement dairy heifers when used in accordance with the following conditions:

(a) The additive meets the following specifications:

| Component/property | Limitation |
|--------------------------------|--|
| Inherent viscosity | 1.0-1.6 deciliter per gram. ¹ |
| Styrene moiety | 40 percent maximum. |
| 2-Vinylpyridine moiety. | 90 percent maximum. |
| Residual styrene | 200 parts per billion maximum. |
| Residual 2-vinylstyrene | 200 parts per billion maximum. |
| Heavy metals such as lead | 10 parts per million maximum. |
| Arsenic | 3 parts per million maximum. |

¹ Inherent viscosity of a 0.25 percent (weight/volume) solution in dimethylformamide.

(b) The additive is used in the manufacture of rumen-stable, abomasum-dispersible nutrient(s) for beef cattle and dairy cattle and replacement dairy heifers such that the maximum use of the additive from all sources does not exceed 5.1 grams per head per day. The additive may be used to protect the following nutrients:

(1) *Methionine*. The resulting product must contain a maximum of 10 percent poly(2-vinylpyridine-co-styrene) by weight and a minimum of 55 percent methionine by weight. The coated methionine must be established through in vitro tests to be at least 90 percent rumen-stable, of which at least 90 percent is subsequently dispersible under abomasal conditions.

(2) *Methionine and lysine*. The resulting product must contain a maximum of 10 percent poly(2-vinylpyridine-co-styrene) by weight and a minimum of a combined total of 55 percent methionine and lysine by weight. The coated methionine and lysine must be established through in vitro tests to be at least 90 percent rumen-stable, of which at least 90 percent is subsequently dispersible under abomasal conditions.

(c) *Label and labeling*. To ensure safe use of the additive, the label and labeling of the additive and of any feed additive supplement, feed additive concentrate, feed additive premix, or liquid feed supplement prepared therefrom, shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the following:

(1) The name of the additive.

(2) A statement of the concentration of poly(2-vinylpyridine-co-styrene) in any product or mixture.

(3) Adequate directions for the use of the rumen-stable, abomasum-dispersible nutrient(s) products.

(4) The following statement: “Warning: Maximum use of poly(2-vinylpyridine-co-styrene) from all sources is not to exceed 5.1 grams per head per day.”

[57 FR 7875, Mar. 5, 1992, as amended at 57 FR 24187, June 8, 1992; 61 FR 11547, Mar. 21, 1996; 70 FR 13100, Mar. 18, 2005]

§ 573.880 Normal propyl alcohol.

Normal propyl alcohol may be safely used in feeds and feed supplements for cattle as a source of metabolizable energy. It is incorporated in the feed or feed supplement in an amount which provides not more than 54.5 grams of the additive per head per day.

§ 573.900 Pyrophyllite.

Pyrophyllite (aluminum silicate monohydrate) may be safely used as the sole anticaking aid, blending agent, pelleting aid, or carrier in animal feed when incorporated therein in an amount not to exceed 2 percent in complete animal feed.

§ 573.914 Salts of volatile fatty acids.

(a) *Identity*. The food additive is a blend containing the ammonium or calcium salt of isobutyric acid and the ammonium or calcium salts of a mixture of 5-carbon acids—isovaleric, 2-methylbutyric, and *n*-valeric.

(b) *Specifications*. The additive contains ammonium or calcium salts of 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 modification 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.