Food and Drug Administration, HHS

§ 573.840 Polysorbate 60.

The food additive polysorbate 60 (polyoxyethylene (20) sorbitan monostearate) may be safely used in animal feeds in accordance with the following prescribed conditions:

- (a) It is used alone or in combination with sorbitan monostearate as an emulsifier in mineral premixes and dietary supplements for animal feeds.
- (b) It is used as an emulsifier in milk-replacer formulations for calves.

§ 573.860 Polysorbate 80.

The food additive polysorbate 80 (polyoxyethylene (20) sorbitan monooleate) may be safely used as an emulsifier in milk-replacer formulations for calves.

§ 573.870 Poly(2-vinylpyridine-co-styrene).

The food additive poly(2-vinylpyridine-co-styrene) may be safely used as nutrient protectant in feed 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 Styrene moiety	1.0-1.6 deciliter per gram. ¹ 40 percent maximum.
2-Vinylpyridine moiety	90 percent maximum.
Residual styrene	200 parts per billion max- imum.
Residual 2-vinylstyrene	200 parts per billion max- imum.
Heavy metals such as lead	10 parts per million max- imum.
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-costyrene) 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.