## Food and Drug Administration, HHS

petrolatum and technical white mineral oil shall not exceed the limits prescribed in paragraph (d) of this section.

(f) Petrolatum may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the act, in an amount not greater than that required to produce its intended effect.

## § 573.740 Odorless light petroleum hydrocarbons.

Odorless light petroleum hydrocarbons complying with §172.884(a) and (b) of this chapter may be safely used in an amount not in excess of that required as a component of insecticide formulations used in compliance with regulations issued in this part.

## §573.750 Pichia pastoris dried yeast.

- (a) *Identity*. The food additive *Pichia* pastoris dried yeast may be used in feed formulations of broiler chickens as a source of protein not to exceed 10 percent by weight of the total formulation.
- (b) *Specifications*. The additive shall conform to the following percent-by-weight specifications:
- (1) Crude protein, not less than 60 percent.
  - (2) Crude fat, not less than 2 percent.
- (3) Crude fiber, not more than 2 percent.
  - (4) Ash, not more than 13 percent.
- (5) Moisture, not more than 6 percent.
- (c) Use. To ensure safe use, the labeling of the additive and any feed additive supplement, concentrate, or premix prepared therefrom shall bear, in addition to other required information, the name of the additive, directions for use to provide not more than 10 percent by weight of the total ration, and the statement "Caution: Not to be used in layers or other poultry intended for breeding."

[58 FR 59170, Nov. 8, 1993]

## §573.760 Poloxalene.

The food additive poloxalene may be safely used in accordance with the following prescribed conditions:

(a) The additive consists of polyoxypropylene-polyoxyethylene glycol nonionic block polymer meeting the following specifications:

- (1) Molecular weight range: 2,850-3,150.
- (2) Hydroxyl number: 35.7–39.4.
- (3) Cloud point (10 percent solution):  $42^{\circ}\,\text{C--}46^{\circ}\,\text{C}.$ 
  - (4) Structural formula:

$$\begin{array}{c} \text{HO(CH}_2 - \text{CH}_2 - \text{O})_{(11\text{-}13)} \\ \text{CH} - \text{CH}_2 - \text{O}_{(32\text{-}36)} \ (\text{CH}_2 - \text{CH}_2 - \text{O})_{(11\text{-}13)} \text{H} \\ \text{CH}_2 \\ \text{CH}_2 \end{array}$$

- (b) In feed as a surfactant for the flaking of feed grains when added to liquid grain conditioner in an amount not to exceed 1.0 percent of the conditioner. The conditioner is added to the feed at a rate of 1 quart per ton of feed.
- (c) The label and labeling shall bear, in addition to the other information required by the Act:
  - (1) The name of the additive.
- (2) Adequate directions and warnings for use.

## § 573.780 Polyethylene.

- (a) *Identity*. Polyethylene consists of basic polymers manufactured by the catalytic polymerization of ethylene.
- (b) Specifications. (1) For the purposes of this section, polyethylene shall meet the specifications in item 2.1 of §177.1520(c) of this chapter.
- (2) The polyethylene is designed in a pellet form in a configuration presenting maximum angular surface having the following dimensions in centimeters:

## $0.9{\pm}0.1 \ge 0.8{\pm}0.1 \ge 1.2{\pm}0.1$

- (c) *Use*. It is used as a replacement for roughage in feedlot rations for finishing slaughter cattle.
- (d) *Labeling*. The labels and labeling shall bear in addition to the other information required by the Act:
- (1) The name of the additive "polyethylene roughage replacement."
- (2) Adequate directions for use which shall provide for the administration of one-half pound of polyethylene pellets per head per day for 6 successive days. All natural roughage should be removed for a minimum of 12 hours prior to administration of polyethylene

#### § 573.800

roughage replacement. Roughage replacement must be adequately mixed in the ration for uniform distribution.

 $[41\ {\rm FR}\ 38652,\ {\rm Sept.}\ 10,\ 1976,\ {\rm as\ amended}\ {\rm at}\ 54\ {\rm FR}\ 18282,\ {\rm Apr.}\ 28,\ 1989]$ 

## § 573.800 Polyethylene glycol (400) mono- and dioleate.

- (a) The food additive polyethylene glycol (400) mono- and dioleate meets the following specifications: Saponification number, 80–88; acid number, 5.0 maximum; and average molecular weight range, 640–680.
- (b) It is used as a processing aid in the production of animal feeds when present as a result of its addition to molasses in an amount not to exceed 250 parts per million of the molasses.

## § 573.820 Polyoxyethylene glycol (400) mono- and dioleates.

The food additive polyoxyethylene glycol (400) mono- and dioleates may be safely used as an emulsifier in calfmilk replacer formulations.

## §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.

# $\S\,573.870$ 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. <sup>1</sup> 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 Arsenic	>10 parts per million. >3 parts per million.

- $^{\rm 1} \, \text{Inherent}$  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.