deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(b) If the Commissioner determines that additional time is needed to study and investigate the petition, he shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.

### § 571.102 Effective date of regulation.

A regulation published in accordance with § 571.100(a) shall become effective upon publication in the FEDERAL REGISTER.

### § 571.110 Procedure for objections and hearings.

Objections and hearings relating to food additive regulations under section 409(c), (d), or (h) of the act shall be governed by part 12 of this chapter.

[42 FR 4717, Jan. 25, 1977, as amended at 42 FR 15676, Mar. 22, 1977]

### § 571.115 Application of the cancer clause of section 409 of the act.

Food additives intended for use as an ingredient in food for animals that are raised for food production and that have the potential to contaminate human food with residues whose consumption could present a risk of cancer to people must satisfy the requirements of subpart E of part 500 of this chapter.

[52 FR 49588, Dec. 31, 1987]

### § 571.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

(a) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive.

(b) Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data shall be furnished in the form specified in § 571.1 for submitting petitions.

[42 FR 4717, Jan. 25, 1977; 42 FR 15676, Mar. 22, 1977]

# PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

## Subpart A [Reserved]

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Sec.

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573.620 Menadione dimethylpyrimidinol bisulfite.
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573.637 Methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids).
573.640 Methyl esters of higher fatty acids.
573.660 Methyl glucoside-coconut oil ester.
573.680 Mineral oil.
573.685 Natamycin.
573.696 Feed grade sodium formate.
573.700 Sodium nitrite.
573.720 Petrolatum.
573.740 Odorless light petroleum hydrocarbons.
573.760 Poloxalene.
573.780 Polyethylene.
573.800 Polyethylene glycol (400) mono- and dioleate.
573.820 Polyoxyethylene glycol (400) mono- and dioleates.
573.840 Polysorbate 60.
573.860 Polysorbate 80.
573.870 Poly(2-vinylpyridine-co-styrene).
573.880 Normal propyl alcohol.
573.900 Pyrophyllite.
573.914 Salts of volatile fatty acids.
573.920 Selenium.
573.940 Silicon dioxide.
573.960 Sorbitan monostearate.
573.980 Taurine.
573.1000 Verxite.
573.1010 Xanthan gum.
573.1020 Yellow prussiate of soda.

AUTHORITY: 21 U.S.C. 321, 342, 348.

SOURCE: 41 FR 38652, Sept. 10, 1976, unless otherwise noted.

## Subpart A [Reserved]

## Subpart B—Food Additive Listing

### § 573.120 Acrylamide-acrylic acid resin.

Acrylamide-acrylic acid resin (hydrolized polyacrylamide), only for the purposes of this section as described below, may be safely used in accordance with the following prescribed conditions:

(a) The additive is produced by polymerization of acrylamide with partial hydrolysis, or by copolymerization of acrylamide and acrylic acid with the greater part of the polymer being composed of acrylamide units.

(b) The additive meets the following specifications:

(1) A minimum molecular weight of 3 million.

(2) Viscosity range: 3,000 to 6,000 centipoises at 77 °F in a 1 percent aqueous solution as determined by LVF Brookfield Viscometer or equivalent using a number 6 spindle at 20 r.p.m.

(3) Residual acrylamide: Not more than 0.05 percent.

(c) It is used as a thickener and suspending agent in nonmedicated aqueous suspensions intended for addition to animal feeds.

[41 FR 38652, Sept. 10, 1976, as amended at 45 FR 38058, June 6, 1980]

### § 573.130 Aminoglycoside 3′-phosphotransferase II.

The food additive aminoglycoside 3′-phosphotransferase II may be safely used in the development of genetically modified cotton, oilseed rape, and tomatoes in accordance with the following prescribed conditions:

(a) The food additive is the enzyme aminoglycoside 3′-phosphotransferase II (CAS Reg. No. 58943–39–8) which catalyzes the phosphorylation of certain aminoglycoside antibiotics, including kanamycin, neomycin, and gentamicin.

(b) Aminoglycoside 3′-phosphotransferase II is encoded by the *kan*$^{r}$ gene originally isolated from transposon Tn*5* of the bacterium *Escherichia coli*.

(c) The level of the additive does not exceed the amount reasonably required for selection of plant cells carrying the *kan*$^{r}$ gene along with the genetic material of interest.

[59 FR 26711, May 23, 1994]

### § 573.140 Ammoniated cottonseed meal.

The food additive ammoniated cottonseed meal may be safely used in accordance with the following conditions:

(a) The food additive is the product obtained by the treatment of cottonseed meal with anhydrous ammonia until a pressure of 50 pounds per square inch gauge is reached.

(b) It is used or intended for use in the feed of ruminants as a source of protein and/or as a source of nonprotein nitrogen in an amount not to exceed 20 percent of the total ration.

(c) To assure safe use, the label and labeling of the additive and of any feed additive supplement, concentrate, or premix prepared therefrom shall bear, in addition to the other information required by the act, the following:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from the nonprotein nitrogen.

(3) Directions for use to provide not more than 20 percent of the additive in the total ration.

(4) A statement:

(i) That not more than one-third of the total protein in the feed should come from nonprotein nitrogen sources.

(ii) That the additive is not to be given to debilitated or starved animals.

(iii) ''Warning—This feed should be used only in accordance with directions furnished on the label.''

[41 FR 38652, Sept. 10, 1976, as amended at 42 FR 52397, Sept. 30, 1977]

### § 573.160 Ammoniated rice hulls.

The food additive ammoniated rice hulls may be safely used in accordance with the following prescribed conditions:

(a) The food additive is the product obtained by the treatment of ground rice hulls with monocalcium phosphate and anhydrous ammonia at a temperature of 350 °F and a pressure of 175 pounds per square inch.

(b) It is used or intended for use in the feed of beef cattle as a source of crude fiber and as the sole source of nonprotein nitrogen in an amount not to exceed 20 percent of the total ration.

(c) To assure safe use of the additive, the label and labeling of the additive and of any feed additive supplement, feed additive concentrate, or feed additive premix prepared therefrom, shall contain, in addition to other information required by the act, the following:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from the nonprotein nitrogen.

(3) Directions for use to provide not more than 20 percent of the additive in the total ration, and a prominent statement: ''Warning—This feed should be used only in accordance with the directions furnished on the label.''

### § 573.170 Ammonium formate.

The food additive, ammonium formate, may be safely used in the manufacture of complete swine feeds in accordance with the following prescribed conditions:

(a) The additive is manufactured by the reaction of 99.5 percent ammonia gas and 99 percent formic acid in a continuous loop reactor to produce a solution made up of 37 percent ammonium salt of formic acid and 62 percent formic acid.

(b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine feeds at levels not to exceed 1.2 percent of the complete feed.

(c) To ensure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act (the act), the label and labeling shall contain:

(1) The name of the additive.

(2) Adequate directions for use including a statement that ammonium formate must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds so treated shall be labeled as containing ammonium formate.

(3) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(e) To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and paragraph (d) of this section, the label and labeling shall contain:

(1) Appropriate warnings and safety precautions concerning ammonium formate (37 percent ammonium salt of formic acid and 62 percent formic acid).

(2) Statements identifying ammonium formate in formic acid (37 percent ammonium salt of formic acid and 62 percent formic acid) as a corrosive and possible severe irritant.

(3) Information about emergency aid in case of accidental exposure as follows:

(i) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

(ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

[75 FR 41725, July 19, 2010, as amended at 78 FR 42692, July 17, 2013; 82 FR 52209, Nov. 13, 2017]

### § 573.180 Anhydrous ammonia.

(a) The food additive anhydrous ammonia is applied directly to corn plant material and thoroughly blended prior to ensiling. It is used or intended for use as a source of nonprotein nitrogen in cattle feed in accordance with paragraphs (a)(1), (2), or (3) as follows:

(1)(i) The food additive anhydrous ammonia is applied as a component of an aqueous premix containing 16 to 17 percent ammonia, with molasses, minerals, and not less than 83 percent crude protein. The premix is a source of nonprotein nitrogen and minerals.

(ii) In addition to the requirements of paragraph (b) of this section, the labeling shall bear an expiration date of not more than 10 weeks after date of manufacture; a statement that additional protein should not be fed to lactating dairy cows producing less than 32 pounds of milk per day nor beef cattle consuming less than 1 percent of body weight daily in shelled corn; and a warning not to use additional trace mineral supplementation with treated silage.

(2)(i) The food additive anhydrous ammonia is applied directly to corn plant material for use in dairy or beef cattle rations.

(ii) The anhydrous ammonia is applied at a rate not to exceed the equivalent of 0.35 percent of the corn plant material.

(iii) It is applied to corn plant material containing 30 to 35 percent dry matter.

(iv) It is applied so that 75 to 85 percent of the additive is liquid at ambient pressure.

(3)(i) The food additive anhydrous ammonia is applied after being diluted to a 15 to 30 percent aqueous ammonia solution (by weight).

(ii) The anhydrous ammonia solution is applied at a rate not to exceed anhydrous ammonia equivalent to 0.3 percent of the corn plant material.

(iii) It is applied to corn plant material containing 28 to 38 percent dry matter.

(iv) The silage treated with aqueous ammonia is to be fed to dairy cattle only.

(b) Its labeling shall bear, in addition to the other requirements of the act, the name of the additive, the concentration of ammonia, the maximum percentage of equivalent crude protein from nonprotein nitrogen, and directions for use consistent with this section.

[44 FR 40284, July 10, 1979]

### § 573.200 Condensed animal protein hydrolysate.

(a) *Identity.* The condensed animal protein hydrolysate is produced from the meat byproducts scraped from cured (salted) hides taken from cattle slaughtered for food consumption. The meat byproduct is hydrolyzed with heat and phosphoric acid.

(b) *Specifications.* The additive shall conform to the following percent-by-weight specifications:

Moisture, not less than 45 percent nor more than 50 percent.
Protein, not less than 24 percent.
Salt (NaCl), not more than 15 percent.
Phosphorus, not less than 2.25 percent.

(c) *Uses.* It is used or intended for use as a source of animal protein, phosphorus, and salt (NaCl) as follows:

(1) In poultry and swine feed in an amount not to exceed 5 percent by weight of the feed.

(2) In feed concentrates for cattle in an amount not to exceed 10 percent by weight of the concentrate.

(d) *Labeling.* The label and labeling shall bear, in addition to the other information required by the act:

(1) The name of the additive, condensed animal protein hydrolysate.

(2) Adequate directions for use including maximum quantities permitted for each species and a guaranteed analysis of the additive.

### § 573.210 Benzoic acid.

The food additive, benzoic acid, may be safely used in the manufacture of complete swine feeds in accordance with the following prescribed conditions:

(a) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine feeds at levels not to exceed 0.5 percent of the complete feed.

(b) The additive consists of not less than 99.5 percent benzoic acid (CAS 65–85–0) by weight with the sum of 2-methylbiphenyl, 3-methylbiphenyl, 4-methylbiphenyl, benzyl benzoate, and isomers of dimethylbiphenyl not to exceed 0.01 percent by weight.

(c) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and paragraph (b) of this section, the label and labeling shall contain:

(1) The name of the additive.

(2) Adequate directions for use including a statement that benzoic acid must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds so treated shall be labeled as containing benzoic acid.

(3) Appropriate warnings and safety precautions concerning benzoic acid.

(4) A warning statement identifying benzoic acid as a possible irritant.

(5) Information about emergency aid in case of accidental exposure.

(6) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

[79 FR 14176, Mar. 13, 2014]

### § 573.220 Feed-grade biuret.

The food additive feed grade biuret may be safely used in ruminant feed in accordance with the following prescribed conditions:

(a) The food additive is the product resulting from the controlled pyrolysis of urea conforming to the following specifications:

| | Percent |
|---|---|
| Biuret | 55 minimum. |
| Urea | 15 maximum. |
| Cyanuric acid and triuret | 30 maximum. |
| Mineral oil | 0.5 maximum. |
| Total nitrogen (equivalent to 218.75 pct crude protein). | 35 minimum. |

(b) It is used in ruminant feeds as a source of nonprotein nitrogen.

(c) To assure safe use of the additive:

(1) The label and labeling of the additive and that of any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall contain, in addition to other information required by the act, the following:

(i) The name of the additive.

(ii) The maximum percentage of equivalent crude protein from nonprotein nitrogen.

(2) The label shall recommend that the diet be balanced to provide adequate nutrients when equivalent crude protein from all forms of nonprotein nitrogen exceed one-third of the total crude protein in the total daily ration.

[41 FR 38652, Sept. 10, 1976, as amended at 68 FR 27904, May 22, 2003]

### § 573.225 1,3-Butylene glycol.

The food additive 1,3-butylene glycol (1,3-butanediol) may be safely used in accordance with the following prescribed conditions:

(a) It complies with the specifications in § 173.220(a) of this chapter.

(b) It is intended for use in swine feed as a source of energy.

(c) It is to be thoroughly mixed into feed at levels not to exceed 9 percent of the dry matter of the total ration.

(d) 1,3-Butylene glycol should be mixed in feed with equipment adapted for the addition of liquids, and the feed should be mixed not less than 5 minutes after its addition.

[53 FR 40061, Oct. 13, 1988]

### § 573.230 Calcium formate.

The food additive calcium formate may be safely used in the manufacture of complete swine and poultry feeds in accordance with the following prescribed conditions:

(a) The additive is manufactured by the reaction of butyraldehyde, formaldehyde, calcium hydroxide, and formic acid in water followed by purification and dried to produce a powder consisting of not less than 99.0 percent

calcium formate (CAS 544–17–2). The additive meets the following specifications:

(1) The additive consists of minimum 30.5 percent calcium and minimum 68.5 percent formate.

(2) Trimethylolpropane (TMP) not to exceed 125 parts per million.

(b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine or poultry feeds at levels not to exceed 1.2 percent of the complete feed.

(c) To ensure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(d) To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling shall contain:

(1) The name of the additive.

(2) Adequate directions for use including a statement that calcium formate must be uniformly applied and thoroughly mixed into complete feeds and that the complete feeds so treated shall be labeled as containing calcium formate.

(3) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(e) To ensure safe use of the additive, in addition to the other information required by the act and paragraph (d) of this section, the label and labeling shall contain:

(1) Appropriate warnings and safety precautions concerning calcium formate.

(2) Statements identifying calcium formate as a possible severe irritant.

(3) Information about emergency aid in case of accidental exposure as follows.

(i) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act, and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

(ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Safety Data Sheet (SDS).

[88 FR 87671, Dec. 19, 2023]

### § 573.240 Calcium periodate.

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

(a) The additive is produced by reacting calcium iodate with calcium hydroxide or calcium oxide to form a substance consisting of not less than 60 percent by weight of penta calcium orthoperiodate containing 28 to 31 percent by weight of iodine.

(b) It is used or intended for use in salt for livestock as a source of iodine.

### § 573.260 Calcium silicate.

Calcium silicate, including synthetic calcium silicate, may be safely used as an anticaking agent in animal feed, provided that the amount of calcium silicate does not exceed 2 percent.

### § 573.280 Feed-grade calcium stearate and sodium stearate.

Feed-grade calcium stearate and sodium stearate may be safely used in an animal feed in accordance with the following prescribed conditions:

(a) Feed-grade calcium stearate and sodium stearate are the calcium or sodium salts of a fatty acid mixture that is predominately stearic acid. Associated fatty acids, including palmitic acid and minor amounts of lauric, myristic, pentadecanoic, margaric, arachidic, and other fatty acids may be contained in the mixture, but such associated fatty acids in aggregate do not exceed 35 percent by weight of the mixture. The fatty acids may be derived from feed-grade fats or oils.

(b) The additives meet the following specifications:

(1) Unsaponifiable matter does not exceed 2 percent.

(2) They are free of chick-edema factor.

(c) The additives are manufactured so that in aqueous solution they are exposed for 1 hour or longer to temperature in excess of 180 °F.

(d) They are used as anticaking agents in animal feeds in accordance

with current good manufacturing practices.

[63 FR 8573, Feb. 20, 1998]

### § 573.300 Choline xanthate.

Choline xanthate may be safely used as a component of animal feed as an added source of choline to supplement the diets of poultry, ruminants, and swine in accordance with good feeding practice.

### § 573.304 Chromium propionate.

The food additive chromium propionate may be safely used in animal feed as a source of supplemental chromium in accordance with the following prescribed conditions:

(a) The additive is manufactured by the reaction of a chromium salt with propionic acid, at an appropriate stoichiometric ratio, to produce triaqua-($mu_3$-oxo) hexakis ($mu_2$-propionato-*O*,*O*′) trichromium propionate with the empirical formula, $[Cr_3(O)(CH_3CH_2CO_2)_6(H_2O)_3]CH_3CH_2CO_2$.

(b) The additive is added to feed as follows:

(1) In complete feed for broiler chickens and growing turkeys at a level not to exceed 0.2 milligrams (mg) of chromium from chromium propionate per kilogram feed.

(2) In feed for horses at a level not to exceed an intake of 4 mg of chromium from chromium propionate per horse per day.

(c) The additive meets the following specifications:

(1) Total chromium content, 8 to 10 percent.

(2) Hexavalent chromium content, less than 2 parts per million (ppm).

(3) Arsenic, less than 1 ppm.

(4) Cadmium, less than 1 ppm.

(5) Lead, less than 0.5 ppm.

(6) Mercury, less than 0.5 ppm.

(7) Viscosity, not more than 2,000 centipoise.

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

(1) It shall be incorporated into each ton of feed by adding no less than one pound of a premix containing no more than 181.4 milligrams of added chromium from chromium propionate per pound.

(2) The premix manufacturer shall follow good manufacturing practices in the production of chromium propionate premixes. Inventory, production, and distribution records must provide a complete and accurate history of product production.

(3) Chromium from all sources of supplemental chromium cannot exceed:

(i) A level of 0.2 ppm in complete feed for broiler chickens and growing turkeys.

(ii) An intake of 4 mg per horse per day.

(e) To assure safe use of the additive in addition to the other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The label and labeling of the additive, any feed premix, and feed shall contain the name of the additive.

(2) The label and labeling of the additive and any feed premix shall also contain:

(i) A guarantee for added chromium content.

(ii) Adequate directions for use and cautions for use including these statements: ''Caution: Follow label directions'' and consistent with the directions for use, the following:

(A) For feed for broiler chickens and growing turkeys, ''Chromium from all sources of supplemental chromium cannot exceed 0.2 parts per million of the complete feed.''

(B) For feed for horses, ''Chromium from all sources of supplemental chromium cannot exceed 4 milligrams per horse per day.''

[81 FR 35611, June 3, 2016, as amended at 85 FR 14566, Mar. 13, 2020; 85 FR 48650, Aug. 12, 2020; 89 FR 5768, Jan. 30, 2024]

### § 573.310 Crambe meal, heat toasted.

(a) The additive is the seed meal of *Crambe abyssinica* obtained after the removal of oil from the seed and hull. The oil may be removed by pre-press solvent extraction or by solvent extraction alone. The resulting seed meal is heat toasted.

(b) The additive conforms to the following percent-by-weight specifications: moisture, not more than 11 percent; oil, not more than 4 percent; crude protein, not less than 24 percent; crude fiber, not more than 26 percent; glucosinolate calculated as epiprogoitrin, not more than 4 percent; goitrin, not more than 0.1 percent;

nitrile calculated as 1-cyano-2-hydroxy-3-butene, not more than 1.4 percent. At least 50 percent of the nitrogen shall be soluble in 0.5 *M* sodium chloride. Myrosinase enzyme activity shall be absent.

(c) The additive is used or intended for use in the feed of feedlot cattle as a source of protein in an amount not to exceed 4.2 percent of the total ration.

[46 FR 30082, June 5, 1981]

### § 573.320 Diammonium phosphate.

The food additive diammonium phosphate may be safely used in ruminant feed in accordance with the following prescribed conditions:

(a) The food additive is the product resulting from the neutralization of feeding-phosphoric-acid or defluorinated wet-process phosphoric acid with anhydrous ammonia. It contains not less than 106.25 percent equivalent crude protein (nitrogen × 6.25) and 20 percent phosphorus. It contains not more than the following:

1 part fluorine to 100 parts phosphorus.
75 parts per million or arsenic (as As).
30 parts per million of heavy metals, as lead (Pb).

(b) It is used in ruminant feeds as a source of phosphorus and nitrogen in an amount that supplies not more than 2 percent of equivalent crude protein in the total daily ration.

(c) To assure safe use of the additive, the label and labeling of the additive and that of any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall contain, in addition to other information required by the act, the following:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from the nonprotein nitrogen.

(3) If the feed additive premix, feed additive concentrate, or feed additive supplement contains more than 2 percent equivalent crude protein from diammonium phosphate, adequate directions for use and a prominent statement, ''Warning—This feed should be used only in accordance with directions furnished on the label.''

### § 573.340 Diatomaceous earth.

(a) *Identity.* The additive consists of siliceous skeletal material derived from various species of diatoms.

(b) *Specifications.* The additive shall conform to the following specifications:

Lead, not more than 15 parts per million.
Arsenic (as As), not more than 20 parts per million
Fluorine, not more than 600 parts per million.

(c) *Uses.* It is used or intended for use as an inert carrier or anticaking agent in animal feeds in an amount not to exceed 2 percent by weight of the total ration.

### § 573.360 Disodium EDTA.

The food additive disodium EDTA (disodium ethylenediaminetetraacetate) may be safely used in animal feeds, in accordance with the following prescribed conditions:

(a) The food additive contains a minimum of 99 percent disodium ethylenediaminetetraacetate dihydrate ($C_{10}H_{14}O_8N_2Na_2 \cdot 2H_2O$).

(b) It is used to solubilize trace minerals in aqueous solutions, which are then added to animal feeds.

(c) It is used or intended for use in an amount not to exceed 240 parts per million of the additive in finished feed.

(d) To assure safe use of the additive the label and labeling shall bear:

(1) The name of the additive; and

(2) Adequate mixing directions to ensure that the chelated trace-mineral mix is uniformly blended throughout the feed.

### § 573.380 Ethoxyquin in animal feeds.

Ethoxyquin (1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline) may be safely used in animal feeds, when incorporated therein in accordance with the following prescribed conditions.

(a) It is intended for use only: (1) As a chemical preservative for retarding oxidation of carotene, xanthophylls, and vitamins A and E in animal feed and fish food and, (2) as an aid in preventing the development of organic peroxides in canned pet food.

(b) The maximum quantity of the additive permitted to be used and to remain in or on the treated article shall not exceed 150 parts per million.

(c) To assure safe use of the additive, the label and labeling of the food additive container and that of any intermediate premixes prepared therefrom shall contain, in addition to other information required by the act:

(1) The name of the additive, ethoxyquin.

(2) A statement of the concentration or strength contained therein.

(3) Adequate use directions to provide for a finished article with the proper concentration of the additive as provided in paragraph (b) of this section, whether or not intermediate premixes are to be used.

(d) The label of any animal feed containing the additive shall, in addition to the other information required by the act, bear the statement ''Ethoxyquin, a preservative'' or ''Ethoxyquin added to retard the oxidative destruction of carotene, xanthophylls, and vitamins A and E.''

### § 573.400 Ethoxyquin in certain dehydrated forage crops.

Ethoxyquin (1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline) may be safely used in the dehydrated forage crops listed in paragraph (a) of this section when incorporated therein in accordance with the conditions prescribed in this section:

(a) It may be added to dehydrated forage prepared from:

| | |
|---|---|
| Alfalfa | Medicago sativa. |
| Barley | Hordeum vulgare. |
| Clovers: | |
| Alsike clover | Trifolium hybridum. |
| Crimson clover | Trifolium incarnatum. |
| Red clover | Trifolium pratense. |
| White clover (including Ladino). | Trifolium repens. |
| White sweetclover | Melilotus alba. |
| Yellow sweetclover | Melilotus officinalis. |
| Coastal Bermudagrass | Cynodon dactylon. |
| Corn | Zea mays. |
| Fescue | Festuca sp. |
| Oats | Avena sativa. |
| Orchardgrass | Dactylis glomerata. |
| Reed canarygrass | Pharlaris arundinacea. |
| Ryegrass (annual and perennial). | Elymus sp. and Lolium perenne. |
| Sorghums | Sorghum vulgare vars, feterita, shallu, kaoliang, broomcorn. |
| Sudan grass | Sorghum vulgare sudanense. |
| Wheat | Triticum aestivum. |

or any mixture of such forage crops, for use only as an animal feed.

(b) Such additive is used only as a chemical preservative for the purpose of retarding oxidative destruction of naturally occurring carotenes and vitamin E in the forage crops.

(c) It is added to the dehydrated forage crops in an oil mixture containing only suitable animal or suitable vegetable oil, prior to grinding and mixing.

(d) The maximum quantity of the additive permitted to be used and to remain in or on the dehydrated forage crop shall not exceed 150 parts per million.

(e) To assure the safe use of the additive, the label of the market package shall contain, in addition to other information required by the act:

(1) The name of the additive as specified in this section.

(2) Directions for the incorporation of the additive in the forage crops, as specified in paragraph (c) of this section, with the directive that only suitable animal or suitable vegetable oils are to be used in the oil mix.

(f) The label of any dehydrated forage crops treated with the additive or the label of an animal-feed supplement containing such treated forage crops, shall, in addition to other information required by the act, bear the following statements:

(1) ''Ethoxyquin, a preservative,'' or ''Ethoxyquin added to retard the oxidative destruction of carotene and vitamin E.''

(2) The statement ''For use in animal feed only.''

### § 573.420 Ethyl cellulose.

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

(a) The food additive is a cellulose ether containing ethoxy ($OC_2H_5$) groups attached by an ether linkage and containing on an anhydrous basis not more than 2.6 ethoxy groups per anhydroglucose unit.

(b) It is used or intended for use:

(1) As a binder or filler in dry vitamin preparations to be incorporated into animal feed.

(2) As a matrix scaffolding for tracers, and the ethyl cellulose content

shall not exceed 80 percent of the tracer.

[41 FR 38652, Sept. 10, 1976, as amended at 89 FR 48508, June 7, 2024]

### § 573.440 Ethylene dichloride.

The food additive ethylene dichloride may be safely used in the manufacture of animal feeds in accordance with the following prescribed conditions:

(a) It is used as a solvent in the extraction processing of animal byproducts for use in animal feeds.

(b) The maximum quantity of the additive permitted to remain in or on the extracted byproducts shall not exceed 300 parts per million.

(c) The extracted animal byproduct is added as a source of protein to a total ration at levels consistent with good feeding practices, but in no event at levels exceeding 13 percent of the total ration.

### § 573.450 Fermented ammoniated condensed whey.

(a) *Identity.* The product is produced by the *Lactobacillus delbrueckii* fermentation of whey with the addition of ammonia.

(b) *Specifications.* The product contains 35 to 55 percent crude protein and not more than 42 percent equivalent crude protein from nonprotein nitrogen sources.

(c) *Uses.* The product is used as a source of protein and nonprotein nitrogen for cattle.

(d) *Limitations.* (1) Store in a closed vented tank equipped for agitation. Agitate 5 minutes before using. Do not store at temperature above 110 °F (43 °C).

(2) The maximum level of use of fermented ammoniated condensed whey and equivalent crude protein from all other added forms of nonprotein nitrogen shall not exceed 30 percent of the dietary crude protein.

(3) The additive may be used as follows:

(i) Mixed with grain, roughage, or grain and roughage prior to feeding.

(ii) As a component of free-choice liquid feeds, used to supplement the diets of cattle fed other sources of nutrients, fermented ammoniated condensed whey shall not exceed 80 percent of the free-choice liquid feed.

(e) *Labeling.* The label shall bear, in addition to other information required by the act:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from nonprotein nitrogen.

(3) Adequate directions for use in accordance with the provisions in paragraph (d) of this section.

[43 FR 33708, July 1, 1978, as amended at 46 FR 49115, Oct. 6, 1981; 89 FR 67856, Aug. 22, 2024]

### § 573.460 Formaldehyde.

The food additive formaldehyde may be safely used in the manufacture of animal feeds in accordance with the following conditions:

(a) The additive is used, or intended for use, to improve the handling characteristics of fat by producing a dry, free-flowing product, as follows:

(1) For animal fat in combination with certain oilseed meals, as a component of dry, nonpelletted feeds for beef and nonlactating dairy cattle.

(i) An aqueous blend of soybean and sunflower meals in a ratio of 3:1, respectively, is mixed with animal fat such that the oilseed meals and animal fat are in a ratio of 3:2. The feed ingredients are those defined by the ''Official Publication'' of the Association of American Feed Control Officials, Inc., 2003 ed., pp. 303, 308, and 309, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the Assistant Secretary-Treasurer, Association of American Feed Control Officials Inc., P.O. Box 478, Oxford, IN 47971, or you may examine a copy at the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(ii) Formaldehyde (37 percent solution) is added to the mixture at a level of 4 percent of the dry matter weight of

the oilseed meals and animal fat. This mixture, upon drying, contains not more than 1 percent formaldehyde and not more than 12 percent moisture.

(iii) To assure the safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act (the act), the label and labeling of the dried mixture shall bear:

(A) The name of the additive.

(B) Adequate directions for use providing that the feed as consumed does not contain more than 25 percent of the mixture.

(2) For soybean and canola seeds and/or meals to which there may be added vegetable oil as a component of dry, nonpelleted feeds for beef and dairy cattle, including lactating dairy cattle.

(i) An aqueous blend of oilseed and/or meals, with or without added vegetable oil, in a ratio such that, on a dry matter basis, the final protein level will be 25 to 35 percent and the fat content will be 20 to 45 percent. The feed ingredients are those defined by the ''Official Publication'' of the Association of American Feed Control Officials, Inc., 2003 ed., pp. 301, 307, 308, and 309, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the Assistant Secretary-Treasurer, Association of American Feed Control Officials Inc., P.O. Box 478, Oxford, IN 47971, or you may examine a copy at the Dockets Management Staff, Food and Drug Administration, 5630 Fishers lane, rm. 1061, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(ii) Formaldehyde (37 percent solution) is added to the mixture at a level of 2.7 percent of the dry matter weight basis of the oilseeds and/or meals and the vegetable oil. This mixture, upon drying, contains not more than 0.5 percent formaldehyde and not more than 12 percent moisture.

(iii) To assure the safe use of the additive, in addition to the other information required by the act, the label and labeling of the dried mixture shall bear:

(A) The name of the additive.

(B) The statement, ''This supplement is not to exceed 12.5% of the total ration. Dietary calcium and magnesium levels should be considered when supplementing the diet with fat.''

(C) The minimum and maximum levels of crude fat must be guaranteed and must be between −5 percent and +5 percent of the analyzed fat content for each batch.

(b)(1) The food additive is formaldehyde (CAS No. 50–00–0; 37 percent aqueous solution). It is used at a rate of 5.4 pounds (2.5 kilograms) per ton of animal feed or feed ingredient. It is an antimicrobial agent used to maintain complete animal feeds or feed ingredients *Salmonella* negative for up to 21 days.

(2) To assure safe use of the additive, in addition to the other information required by the Act, the label and labeling shall contain:

(i) The name of the additive.

(ii) A statement that formaldehyde solution which has been stored below 40 °F or allowed to freeze should not be applied to complete animal feeds or feed ingredients.

(iii) Adequate directions for use including a statement that formaldehyde should be uniformly sprayed on and thoroughly mixed into the complete animal feeds or feed ingredients and that the complete animal feeds or feed ingredients so treated shall be labeled as containing formaldehyde. The label must prominently display the statement: ''Treated with formaldehyde to maintain feed *Salmonella* negative. Use within 21 days.''

(iv) The labeling for feed or feed ingredients to which formaldehyde has been added under the provisions of paragraph (b)(1) of this section is required to carry the following statement: ''Treated with formaldehyde to maintain feed *Salmonella* negative. Use within 21 days.''

(3) To assure safe use of the additive, in addition to the other information required by the Act, the label and labeling shall contain:

(i) Appropriate warnings and safety precautions concerning formaldehyde.

(ii) Statements identifying formaldehyde as a poison with potentials for adverse respiratory effects.

(iii) Information about emergency aid in case of accidental inhalation.

(iv) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

(v) Contact address and phone number for reporting adverse reactions or to request a copy of the Materials Safety Data Sheet (MSDS).

[41 FR 38652, Sept. 10, 1976, as amended at 54 FR 18281, Apr. 28, 1989; 61 FR 15704, Apr. 9, 1996; 63 FR 53580, Oct. 6, 1998; 68 FR 65633, Nov. 21, 2003; 88 FR 45066, July 14, 2023]

### § 573.480 Formic acid.

The food additive, formic acid, may be safely used in accordance with the following conditions:

(a) The additive is used as a preservative in hay crop silage in an amount not to exceed 2.25 percent of the silage on a dry weight basis or 0.45 percent when direct cut, as follows:

(1) The top foot of silage stored should not contain formic acid and

(2) Silage should not be fed to livestock within 4 weeks of treatment.

(b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete feed for swine and poultry at levels not to exceed 1.2 percent of the complete feed.

(1) The additive consists of not less than 85 percent formic acid (CAS 64–18–6).

(2) The additive meets the following specifications:

(i) Free methyl alcohol not to exceed 1,000 parts per million (ppm);

(ii) Methyl formate not to exceed 1,000 ppm; and

(iii) Moisture not to exceed 15 percent.

(3) To ensure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(4) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug and Cosmetic Act, the label and labeling shall contain:

(i) The name of the additive.

(ii) Adequate directions for use including a statement that formic acid must be uniformly applied and thoroughly mixed into complete feeds and that the complete feeds so treated shall be labeled as containing formic acid.

(iii) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(5) To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and paragraph (b)(4) of this section, the label and labeling shall contain:

(i) Appropriate warnings and safety precautions concerning formic acid (85 percent formic acid).

(ii) Statements identifying formic acid (85 percent formic acid) as a corrosive and possible severe irritant.

(iii) Information about emergency aid in case of accidental exposure.

(A) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

(B) Contact address and telephone number for reporting adverse reactions or to request a copy of the Safety Data Sheet (SDS).

[76 FR 7106, Feb. 9, 2011, as amended at 82 FR 52209, Nov. 13, 2017; 83 FR 20, Jan. 2, 2018; 83 FR 66618, Dec. 27, 2018]

### § 573.485 Fumonisin esterase.

The food additive fumonisin esterase may be safely used to degrade fumonisins in swine and poultry feed in accordance with the following prescribed conditions:

(a) Fumonisin esterase, a carboxylesterase, is produced by a nontoxigenic and nonpathogenic yeast,

*Komagataella phaffii*, genetically engineered to express the fumonisin esterase gene from the bacterium *Sphingopyxis* sp. Hydrolyzed fumonisin and two tricarballylic acid molecules are the reaction products of fumonisin hydrolysis by this 493 amino acid fumonisin esterase enzyme.

(b) The additive shall meet the following specifications:

(1) The fermentation media for the *Komagataella phaffii* shall not contain methanol.

(2) Viable genetically engineered *Komagataella phaffii* shall not be present.

(3) One unit of fumonisin esterase activity is defined as the amount of enzymatic activity required to release one micromole of tricarballylic acid (CAS 99–14–9) per minute from 100 micromolar fumonisin B1 in 20 millimolar Tris-hydrochloride buffer (pH 8.0) containing 0.1 milligram per milliliter of bovine serum albumin at 30 °C.

(c) The additive is incorporated at a minimum of 15 units of fumonisin esterase activity per kilogram of complete feed:

(1) Complete swine feeds cannot contain more than 10 parts per million of total fumonisins.

(2) Complete feed for poultry being raised for slaughter cannot contain more than 50 parts per million of total fumonisins.

(3) Complete feed for breeding poultry and hens laying eggs for human consumption cannot contain more than 15 parts per million of total fumonisins.

(d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The label and labeling of the additive, any feed premix, and complete feed shall contain the common or usual name of the additive's source, dried *Komagataella phaffii* fermentation product.

(2) The label and labeling of the additive and any feed premix shall also contain:

(i) Adequate directions for use including a statement that the additive must be uniformly applied and thoroughly mixed into complete feeds;

(ii) A guarantee for the minimum amount of fumonisin esterase activity, expressed in accordance with paragraph (b)(3) of this section, and the unit of weight being consistent with the inclusion rate stated in the directions for use;

(iii) Appropriate warning and safety precaution statements concerning the additive as a respiratory sensitizer;

(iv) A cautionary statement concerning the maximum fumonisin content as established in paragraph (c) of this section.

[87 FR 47344, Aug. 3, 2022, as amended at 87 FR 52682, Aug. 29, 2022]

### § 573.490 Gamma-linolenic acid safflower meal.

The food additive consists of the meal obtained after the removal of most of the oil from whole seeds or partially dehulled seeds or both obtained from a *Carthamus tinctorius* L. safflower Centennial variety genetically engineered to express the delta-6-desaturase gene from *Saprolegnia diclina* Humphrey. The 453 amino acid, delta-6-desaturase enzyme converts the fatty acid linoleic acid to gamma-linolenic acid during seed development. The resulting additive may be safely used in cattle and poultry feeds in accordance with the following prescribed conditions:

(a) The additive shall contain not less than 20 percent crude protein, not more than 40 percent crude fiber, not more than 10 percent moisture, and not more than 2 percent crude fat.

(b) The crude fat in the additive meets the following specifications:

(1) Gamma-linolenic acid content not to exceed 55 percent.

(2) Total content of stearidonic acid and cis, cis-6, 9-octadecadienoic acid not to exceed a total of 0.5 percent.

(3) Total content of palmitic, stearic, oleic, linoleic, and other associated fatty acids to exceed a total of 40 percent.

(c) The additive is used or intended for use in cattle and poultry feeds as a source of protein in accordance with good manufacturing and feeding practices.

(d) To assure safe use of the additive, in addition to the other information required by the Food, Drug, and Cosmetic Act, the label and labeling of the additive, any feed premix, or complete feed shall bear the following:

(1) The name of the additive or the common name, safflower meal.

(2) Adequate directions for use in cattle and poultry feeds.

(e) The additive may be identified by the common or usual name, safflower meal.

[80 FR 35569, June 22, 2015]

### § 573.492 Gamma-linolenic acid safflower oil.

The food additive, gamma-linolenic acid safflower oil, may be safely used in animal food as a source of gamma-linolenic acid and other omega-6 fatty acids in accordance with the following conditions:

(a) The additive is the oil obtained from whole seeds and/or partially dehulled seeds of a *Carthamus tinctorius* L. safflower Centennial variety genetically engineered to express the delta-6-desaturase gene from *Saprolegnia diclina* Humphrey. The 453 amino acid, delta-6-desaturase enzyme converts the fatty acid linoleic acid to gamma-linolenic acid (all-*cis*-6,9,12-octadecatrienoic acid) during seed development.

(1) The additive obtained from the seeds of the genetically engineered safflower Centennial variety may be blended with oil obtained from seeds of non-engineered oleic acid safflower varieties in order to meet the specifications required for the additive or the blend in paragraph (a)(2) of this section.

(2) The additive or a safflower oil blend containing the additive for use in animal food meets the following specifications:

(i) Crude fat content of the additive or the safflower oil blend is not less than 99.5 percent.

(ii) Gamma-linolenic acid content is between 350 and 450 milligrams (mg) gamma-linolenic acid per gram of the additive or the safflower oil blend.

(iii) Total content of stearidonic acid and *cis, cis*-6,9-octadecadienoic acid in the additive or the safflower oil blend must not exceed a total of 0.3 percent.

(b) Addition of the additive, or the safflower oil blend, to complete dry adult maintenance dog food must meet the following:

(1) Addition of the additive or the safflower oil blend cannot provide more than 36 mg gamma-linolenic acid per kilogram body weight of the dog per day in more than 86 mg of the additive or the safflower oil blend. This maximum addition rate of the additive, or the safflower oil blend, is 0.3 percent of a complete dry adult maintenance dog food containing 3,600 kilocalories of metabolizable energy per kilogram of food as-fed.

(2) Adjustments must be made for differing concentrations of gamma-linolenic acid and for dog food formulas of different caloric density and/or that are fed to specific weights, breeds, or dogs of different activity levels to meet the requirements of this paragraph.

(c) Addition of the additive, or the safflower oil blend, to complete dry adult maintenance cat food must meet the following:

(1) Addition of the additive or the safflower oil blend cannot provide more than 33 mg gamma-linolenic acid per kilogram body weight of the cat per day in more than 79 mg of the additive or the safflower oil blend. This maximum addition rate of the additive, or the safflower oil blend, is 0.5 percent of a complete dry adult maintenance cat food containing 4,000 kilocalories of metabolizable energy per kilogram of food as-fed.

(2) Adjustments must be made for differing concentrations of gamma-linolenic acid and for cat food formulas of different caloric density and/or that are fed to specific weights, breeds, or cats of different activity levels to meet the requirements of this paragraph.

(d) To assure safe use of the additive, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling of the additive shall bear the following:

(1) The name of the additive, gamma-linolenic acid safflower oil, or GLA safflower oil;

(2) A guarantee for the minimum content of gamma-linolenic acid; and

(3) Adequate directions for use such that the finished animal food complies

with the provisions of paragraphs (b) and (c) of this section.

[84 FR 6675, Feb. 28, 2019]

### § 573.496 Guanidinoacetic acid.

The food additive, guanidinoacetic acid, may be safely used in poultry feeds in accordance with the following prescribed conditions:

(a) The additive is manufactured by reacting glycine with cyanamide in an aqueous solution.

(b) The additive is used or intended for use at levels not to exceed 0.12 percent of the complete feed:

(1) To spare arginine in broiler chicken and turkey feeds; or

(2) As a precursor of creatine in poultry feeds.

(c) The additive consists of not less than 97 percent guanidinoacetic acid [*N*-(aminoiminomethyl)-glycine] (CAS 352–97–6) by weight.

(d) The additive meets the following specifications:

(1) Dicyandiamide not to exceed 0.5 percent;

(2) Cyanamide not to exceed 0.01 percent;

(3) Melamine not to exceed 15 parts per million (ppm);

(4) Sum of ammeline, ammelide, and cyanuric acid not to exceed 35 ppm; and

(5) Water not to exceed 1 percent.

(e) To assure safe use of the additive in addition to the other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The label and labeling of the additive, any feed premix, and complete feed shall contain the name of the additive.

(2) The label and labeling of the additive and any feed premix shall also contain:

(i) A statement to indicate the maximum use level of guanidinoacetic acid must not exceed 0.12 percent of the complete feed for poultry; and

(ii) Adequate directions for use.

[81 FR 86269, Nov. 30, 2016, as amended at 86 FR 37038, July 14, 2021]

### § 573.500 Condensed, extracted glutamic acid fermentation product.

Condensed, extracted glutamic acid fermentation product may be safely used in animal feed under the following conditions:

(a) The additive is a concentrated mixture of the liquor remaining from the extraction of glutamic acid, combined with the cells of *Corynebacterium glutamicum* used to produce the glutamic acid.

(b) It is used or intended for use as follows:

(1) In poultry feed as a source of protein in an amount not to exceed 5 percent of the total ration.

(2) In cattle feed as a source of protein in an amount not to exceed 10 percent of the feed.

(c) In order to assure safe use, the label and labeling of the additive shall bear, in addition to the other information required by the Act, the following:

(1) The name of the additive.

(2) A statement of the concentration of the additive contained in any mixture.

(3) Adequate directions for use.

[41 FR 38652, Sept. 10, 1976, as amended at 89 FR 33231, Apr. 29, 2024]

### § 573.520 Hemicellulose extract.

Hemicellulose extract may be safely used in animal feed when incorporated therein in accordance with the following conditions:

(a) The additive is produced from the aqueous extract obtained by the treatment of wood with water at elevated temperatures (325 degrees–535 degrees F) and pressure (80 to 900 pounds per square inch) and contains primarily pentose and hexose sugars.

(b) The additive may be used in a liquid or dry state with the liquid product containing not less than 55 percent carbohydrate and the dry product containing not less than 84 percent carbohydrate.

(c) The additive is used as a source of metabolizable energy in animal feed in accordance with good manufacturing and feeding practices.

[41 FR 38652, Sept. 10, 1976, as amended at 43 FR 11181, Mar. 17, 1978]

### § 573.530 Hydrogenated corn syrup.

(a) *Identity.* The product is produced by hydrogenation of corn syrup over a nickel catalyst.

(b) *Specifications.* The product contains 70 percent hydrogenated corn syrup and a maximum of 0.5 percent reducing sugars.

(c) *Uses.* The product is used as a humectant and plasticizer in preparation of soft-moist dog and cat foods.

(d) *Limitations.* The product is preferably stored in a closed, stainless steel or aluminum container. The level of use of the product shall not exceed 15 percent of the total weight of the pet food formulation.

(e) *Labeling.* The labeling shall bear, in addition to other information required by the Act:

(1) The name of the additive.

(2) Adequate directions for use in accordance with the provisions in paragraph (d) of this section.

[45 FR 22920, Apr. 4, 1980]

### § 573.540 Hydrolyzed leather meal.

(a) *Identity.* Hydrolyzed leather meal is produced from leather scraps that are treated with steam for not less than 33 minutes at a pressure of not less than 125 pounds per square inch.

(b) *Specifications.* The additive shall conform to the following percent-by-weight specifications:

Moisture, not less than 5 percent nor more than 10 percent.
Crude protein, not less than 60 percent.
Crude fat, not less than 5 percent.
Crude fiber, not more than 6 percent.
Chromium, not more than 2.75 percent.

(c) *Use.* It is used or intended for use as a source of protein in swine feeds in an amount not to exceed 1.0 percent by weight of the finished feed.

(d) *Labeling.* The labels and labeling shall bear, in addition to the other information required by the Act:

(1) The name of the additive, hydrolyzed leather meal.

(2) Adequate directions to provide finished feeds complying with paragraph (c) of this section.

### § 573.550 25-hydroxyvitamin $D_3$.

The food additive, 25-hydroxyvitamin $D_3$, may be safely used in accordance with the following prescribed conditions:

(a) The additive is used or intended for use as a source of vitamin $D_3$ activity in animal feed or drinking water in accordance with good manufacturing and feeding practices as follows:

(1) In feed or drinking water of layer and breeder chickens not to exceed 69 parts per billion (ppb) in feed or 34.5 ppb in drinking water.

(2) In feed or drinking water of turkeys not to exceed:

(i) 92 ppb in feed; or

(ii) In drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.

(b) The additive consists of not less than 94 percent 25-hydroxyvitamin $D_3$ (9,10-secocholesta-5,7,10(19)-triene-3β, 25-diol).

(c) The additive meets the following specifications:

(1) Not more than 1 percent of any individual sterol.

(2) Not more than 5 percent water.

(3) Not more than 20 parts per million (ppm) lead.

(4) Not more than 20 ppm aluminum.

(5) Not more than 1.0 percent solvents and non-detectable levels of 2′, 4′, 5′, 7′ tetraiodofluorescin.

(6) Not more than 1 ppb 1, 25-dihydroxycholecalciferol.

(d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling shall contain:

(1) The name of the additive.

(2) A statement to indicate the maximum use level of 25-hydroxyvitamin $D_3$ must not exceed 69 ppb in feed or 34.5 ppb in drinking water for layer and breeder chickens.

(3) A statement to indicate for turkeys the maximum use level of 25-hydroxyvitamin $D_3$ must not exceed 92 ppb in feed; or in drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.

(4) Adequate use directions to ensure that 25-hydroxyvitamin $D_3$ (and all premixes) is uniformly blended throughout the feed or drinking water.

(5) An expiration date on all premix labeling.

(6) A statement on all premix labeling (feed and drinking water forms) that 25-hydroxyvitamin $D_3$ cannot be

used simultaneously in both feed and water.

[83 FR 49486, Oct. 2, 2018]

### § 573.560 Iron ammonium citrate.

Iron ammonium citrate may be safely used in animal feed in accordance with the following prescribed conditions:

(a) The additive is the chemical green ferric ammonium citrate.

(b) The additive is used or intended for use as an anticaking agent in salt for animal consumption so that the level of iron ammonium citrate does not exceed 25 parts per million (0.0025 percent) in the finished salt.

(c) To assure safe use of the additive the label or labeling of the additive shall bear, in addition to the other information required by the Act:

(1) The name of the additive.

(2) Adequate directions to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

### § 573.580 Iron-choline citrate complex.

Iron-choline citrate complex made by reacting approximately equimolecular quantities of ferric hydroxide, choline, and citric acid may be safely used as a source of iron in animal feed.

### § 573.587 Komagataella pastoris dried yeast.

(a) *Identity.* The food additive *Komagataella pastoris* dried yeast is non-viable and 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. Redesignated and amended at 89 FR 72315, Sept. 5, 2024]

### § 573.600 Lignin sulfonates.

Lignin sulfonates may be safely used in animal feeds in accordance with the following prescribed conditions:

(a) For the purpose of this section, the food additive is either one, or a combination of, the ammonium, calcium, magnesium, or sodium salts of the extract of spent sulfite liquor derived from the sulfite digestion of wood or of abaca (*Musa textilis*) or of sisal (*Agave sisalana*) in either a liquid form (moisture not to exceed 50 percent by weight) or dry form (moisture not to exceed 6 percent by weight).

(b) It is used or intended for use in an amount calculated on a dry weight basis, as follows:

(1) As a pelleting aid in the liquid or dry form in an amount not to exceed 4 percent of the finished pellets.

(2) As a binding aid in the liquid form in the flaking of feed grains in an amount not to exceed 4 percent of the flaked grain.

(3) As a surfactant in molasses used in feeds, as liquid lignin sulfonate, in an amount not to exceed 11 percent of the molasses.

(4) As a source of metabolizable energy, in the liquid or dry form, in an amount not to exceed 4 percent of the finished feed.

### § 573.615 Marine microalgae.

The food additive, marine microalgae, may be safely used as a source of docosahexaenoic acid (DHA) and other omega-3 fatty acids in accordance with the following prescribed conditions:

(a) The additive is dried whole cells of nonviable, nontoxigenic, nonpathogenic *Schizochytrium* sp. algae grown as a pure culture.

(b) The additive is used in complete, dry adult maintenance food for dogs in accordance with good manufacturing and feeding practices not to exceed 16.5 pounds per ton (7.5 kilograms (kg) per

1000 kg) of complete, dry, adult maintenance dog food.

(c) The additive consists of not less than 17.0 percent (4*Z*,7*Z*,10*Z*,13*Z*,16*Z*,19*Z*)-docosa-4,7,10,13,16,19-hexaenoic acid (docosahexaenoic acid or DHA).

(d) The additive meets the following specifications:

(1) Not less than 40 percent crude fat;

(2) Not more than 12 percent ash;

(3) Not more than 8 percent unsaponifiable matter;

(4) Not more than 5 percent insoluble impurities;

(5) Not more than 5 percent free fatty acids; and

(6) Not more than 6 percent water.

(e) To ensure the safe use of the additive, in addition to other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The label and labeling of the additive, any feed premix, and complete feed, shall contain the name of the additive, marine microalgae.

(2) The label and labeling of the additive and any feed premix shall also contain:

(i) A statement to indicate that the maximum use level of the additive shall not exceed 16.5 pounds per ton (7.5 kg per 1000 kg) of complete, dry, adult maintenance dog food.

(ii) Adequate directions for use.

[83 FR 19935, May 7, 2018]

### § 573.620 Menadione dimethylpyrimidinol bisulfite.

The food additive, menadione dimethylpyrimidinol bisulfite, may be safely used in accordance with the following conditions:

(a) The additive is the 2-hydroxy-4,6-dimethylpyrimidinol salt of menadione ($C_{17}H_{18}O_6N_2S$).

(b) The additive is used or intended for use as a nutritional supplement for the prevention of vitamin K deficiency as follows:

(1) In chicken and turkey feed at a level not to exceed 2 grams per ton of complete feed.

(2) In the feed of growing and finishing swine at a level not to exceed 10 grams per ton of feed.

(c) To assure safe use, the label and labeling of the additive shall bear adequate directions for use.

### § 573.625 Menadione nicotinamide bisulfite.

The food additive may be safely used as follows:

(a) The additive is 1,2,3,4-tetrahydro-2-methyl-1,4-dioxo-2-naphthalene sulfonic acid with 3-pyridine carboxylic acid amine (CAS No. 73581–79–0).

(b) The additive is used or intended for use as a nutritional supplement for both the prevention of vitamin K deficiency and as a source of supplemental niacin as follows:

(1) In chicken and turkey feeds at a level not to exceed 2 grams per ton of complete feed.

(2) In growing and finishing swine feeds at a level not to exceed 10 grams per ton of complete feed.

(c) To assure safe use, the label and labeling of the additive shall bear adequate directions for use.

[64 FR 46840, Aug. 27, 1999]

### § 573.637 Methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids).

The food additive, methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids) may be safely used in swine feed and feed for early lactation dairy cows (less than 100 days in milk) in accordance with the prescribed conditions:

(a) The food additive is manufactured by the reaction of refined sunflower oil with methanol to produce fatty acid methyl esters, which then undergo conjugation to yield methyl esters of octadecadienoic acid. The additive consists of not less than 28 percent methyl ester of cis-9, trans-11-octadecadienoic acid, and not less than 28 percent methyl ester of trans-10, cis-12-octadecadienoic acid with the sum of the other methyl esters of octadecadienoic acid not to exceed 4 percent. The additive shall contain not less than 35 percent of other fatty acid esters composed of oleic acid, palmitic acid, stearic acid, linoleic acid, and other associated acid esters.

(b) The additive is used or intended for use in the feed of:

(1) Growing and finishing swine as a source of fatty acids at levels not to exceed 0.6% in the finished feed.

(2) Early lactation dairy cows to reduce the energy concentration in milk when fed at levels not to exceed 33 grams per cow per day.

(c) The additive meets the following specifications:

(1) Free methyl alcohol not to exceed 0.015%.

(2) Insoluble impurities not to exceed 0.1%.

(3) Moisture not to exceed 0.5%.

(4) Unsaponifiable matter not to exceed 1.0%.

(d) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label and labeling of the additive and any feed premix shall bear the following:

(i) The name of the additive.

(ii) A statement to indicate that methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12 octadecadienoic acids) must not be added to vitamin or mineral premixes.

(2) The label and labeling of the additive, any feed premix, or complete feed prepared therefrom shall bear adequate directions for use.

[73 FR 64198, Oct. 29, 2008, as amended at 87 FR 21019, Apr. 11, 2022]

### § 573.640 Methyl esters of higher fatty acids.

The food additive methyl esters of higher fatty acids may be safely used in animal feeds in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reaction of methyl alcohol with feed-grade fats or oils and consists of not less than 70 percent methyl esters of the following straight-chain monocarboxylic acids: Docosahexanoic acid, eicosapentanoic acid, linoleic acid, myristic acid, oleic acid, palmitic acid, palmitoleic acid, and stearic acid, and lesser amounts of the associated acid esters.

(b) The food additive meets the following specifications:

(1) Free methyl alcohol not to exceed 150 parts per million.

(2) Unsaponifiable matter not to exceed 2 percent.

(3) It is free of chick-edema factor or other factors toxic to chicks, as evidenced during the bioassay method for determining the chick-edema factor as prescribed in paragraph (b)(4)(ii) of this section.

(4) For the purposes of this section:

(i) Unsaponifiable matter shall be determined by the method described in Section 28.081, ''Unsaponifiable Residue (20)—Official Final Action'' of the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed., 1980, p. 451, which is incorporated by reference. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(ii) The chick-edema factor bioassay method described under ''26. Oils, Fats, and Waxes'' in the *Journal of the Association of Official Agricultural Chemists*, Vol. 44, Page 146 (1961), or the method described under ''Chick-Edema Factor—Bioassay Method (34)—Official Final Action'' in §§ 28.113–28.117, ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 12th Ed., 1975, pp. 509–511, which is incorporated by reference, shall be employed. (Copies of the methods are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspectionat the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* ) The presence of chick-edema factor shall be determined by a comparison between the mean log of the pericardial fluid volumes of a test group and of a concurrent negative control group. The significance of the difference in pericardial fluid volumes between the test group and the negative control group is determined by calculating a ''*t*'' value according to the formula:

$$t = \frac{\bar{x}_t - \bar{x}_c}{\sqrt{\left(s_t^2/n_t\right) + \left(s_c^2/n_c\right)}}$$

where:

$\bar{x}_t$ and $\bar{x}_c$ are the means of the logs of the pericardial fluid volumes of the test and control groups, respectively;

$n_t$ and $n_c$ are the number of chicks in the respective groups;

$s_t^2$ and $s_c^2$ are the variances of the test and control groups, respectively.

The variances are calculated as follows:

$$s^2 = \frac{n(\sum x^2) - (\sum x)^2}{n(n-1)}$$

where:

$\Sigma x$ is the sum of the logs of the pericardial fluid volumes;

$\Sigma x^2$ is the sum of the squares of the logs of the pericardial fluid volumes for either the test $t$ or control $c$ group data.

The test sample is judged to contain chick-edema factor if the calculated ''$t$'' exceeds +1.3 and the mean log of the pericardial fluid volume obtained from the negative control group multiplied by 100 is less than 1.1461.

(iii) ''Other factors toxic to chicks'' referred to in paragraph (b)(3) of this section shall be determined during the course of the bioassay test described in paragraph (b)(4)(ii) of this section, on the basis of chick deaths or other abnormalities not attributable to chick-edema factor or to the experimental conditions of the test.

(c) It is used or intended for use as a supplementary source of fat for animal feed.

(d) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label and labeling of the additive, and any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall bear:

(i) The name of the additive.

(ii) The designation ''feed grade'' in juxtaposition with the name and equally as prominent.

(2) The label or labeling of the additive and any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall bear adequate directions for use.

[41 FR 38652, Sept. 10, 1976, as amended at 47 FR 9397, Mar. 5, 1982; 54 FR 18281, Apr. 28, 1989; 70 FR 40880, July 15, 2005; 70 FR 67651, Nov. 8, 2005]

### § 573.660 Methyl glucoside-coconut oil ester.

Methyl glucoside-coconut oil ester may be safely used in accordance with the following conditions:

(a) The additive meets the specifications prescribed in § 172.816 of this chapter.

(b) It is used as a surfactant in molasses intended for use in animal feed at a level not to exceed 320 parts per million.

### § 573.680 Mineral oil.

Mineral oil may be safely used in animal feed, subject to the provisions of this section.

(a) Mineral oil, for the purpose of this section, is that complying with the definition and specifications contained in § 172.878 (a) and (b) or in § 178.3620(b)(1) (i) and (ii) of this chapter.

(b) It is used in animal feeds for the following purposes:

(1) To reduce dustiness of feeds or mineral supplements.

(2) To serve as a lubricant in the preparation of pellets, cubes, or blocks and to improve resistance to moisture of such pellets, cubes, or blocks.

(3) To prevent the segregation of trace minerals in mineralized salt.

(4) To serve as a diluent carrier in the manufacture of feed grade biuret in accordance with good manufacturing practice.

(5) For the removal of water from substances intended as ingredients of animal feed.

(c) The quantity of mineral oil used in animal feed shall not exceed 3.0 percent in mineral supplements, nor shall it exceed 0.06 percent of the total ration when present in feed or feed concentrates.

[41 FR 38652, Sept. 10, 1976, as amended at 47 FR 41106, Sept. 17, 1982]

### § 573.685 Natamycin.

The food additive natamycin (CAS No. 7681–93–8) may be safely used in

broiler chicken feeds in accordance with the following specifications:

(a) The additive is a stereoisomer of 22-[(3-amino-3,6,dideoxy-β-D-mannopyranosyl)oxy]-1,3,26-trihydroxy-12-methyl-10-oxo-6,11,28-trioxatricyclo[22.3.1.$0^{5}$, $^{7}$] octacosa-8,14,16,18,20-pentaene-25-carboxylic acid with the empirical formula $C_{33}H_{47}NO_{13}$.

(b) The additive shall conform to U.S.P. specifications.

(c) The additive (as part of a premix composed of calcium carbonate, natamycin, and lactose) is used for retarding the growth of *Aspergillus parasiticus* in broiler chicken feeds for up to 14 days after the addition of natamycin.

(d) Each pound (454 grams (g)) of the premix shall contain 434 (g) of calcium carbonate, 10 g of natamycin activity, and 10 g of lactose. The premix shall be mixed into broiler chicken feed at the rate of 1 pound (0.454 kilograms (kg)) per ton (908 kg) of feed to provide natamycin at a level of 11 parts per million (ppm). The premix shall be thoroughly mixed into the dry components of the broiler chicken feed before adding the liquid components. Broiler feeds to which the natamycin premix is added shall be used within 4 weeks of addition of the premix.

(e) To assure the safe use of the additive, the label or labeling of the additive shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the following:

(1) The name and CAS number of the additive, and its purpose.

(2) A listing of ingredients consisting of calcium carbonate, the additive, and lactose and their proportions in the premix as prescribed under paragraph (d) of this section.

(3) Adequate directions for use to ensure a broiler chicken feed that is in compliance with the limitations prescribed in paragraph (d) of this section.

(4) An appropriate cautionary statement: ''Caution: Store in a tightly-closed, light-resistant container in a cool, dry place.''

(5) An expiration date of 1 year from the date of manufacture.

(6) A contact address and telephone number for reporting adverse reactions experienced by users, or to request a copy of the Material Safety Data Sheet for natamycin.

[69 FR 19321, Apr. 13, 2004]

### § 573.696 Feed grade sodium formate.

The food additive, feed grade sodium formate, may be safely used in the manufacture of complete swine and poultry feeds in accordance with the following prescribed conditions:

(a) The additive is manufactured by the reaction of 99 percent formic acid and 50 percent sodium hydroxide in water to produce a solution made up of at least 20.5 percent sodium salt of formic acid and not more than 61 percent formic acid.

(b) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine and poultry feeds at levels not to exceed 1.2 percent of the complete feed.

(c) To assure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling shall contain:

(1) The name of the additive.

(2) Adequate directions for use, including a statement that feed grade sodium formate must be uniformly applied and thoroughly mixed into complete feeds and that the complete feeds so treated shall be labeled as containing feed grade sodium formate.

(3) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(e) To assure safe use of the additive, in addition to the other information required by the act and paragraph (d) of this section, the label and labeling shall contain:

(1) Appropriate warnings and safety precautions concerning feed grade sodium formate.

(2) Statements identifying feed grade sodium formate as a corrosive and possible severe irritant.

(3) Information about emergency aid in case of accidental exposure as follows:

(i) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration (OSHA) human safety guidance regulations.

(ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

[81 FR 67154, Sept. 30, 2016, as amended at 81 FR 95027, Dec. 27, 2016]

### § 573.700 Sodium nitrite.

Sodium nitrite may be safely used in canned pet food containing meat and fish in accordance with the following prescribed conditions:

(a) It is used or intended for use alone as a preservative and color fixative in canned pet food containing fish, meat, and fish and meat byproducts so that the level of sodium nitrite does not exceed 20 parts per million.

(b) To assure safe use of the additive, in addition to the other information required by the act:

(1) The label of the additive shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive in any mixture.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (a) of this section.

### § 573.720 Petrolatum.

Petrolatum may be safely used in or on animal feed, subject to the following prescribed conditions:

(a) Petrolatum complies with the specifications set forth in the U.S. Pharmacopeia XVI for white petrolatum or in The National Formulary XII for yellow petrolatum.

(b) Petrolatum meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in § 172.886(b) of this chapter.

Ultraviolet absorbance per centimeter path length:

| Millimicrons | Maximum |
|---|---|
| 280 to 289 | 0.25 |
| 290 to 299 | .20 |
| 300 to 359 | .14 |
| 360 to 400 | .04 |

(c) It is used in animal feed for the following purposes:

(1) To reduce dustiness of feeds or mineral supplements.

(2) To serve as a lubricant in the preparation of pellets, cubes, or blocks, and to improve resistance to moisture of such pellets, cubes, or blocks.

(d) The quantity of petrolatum present in animal feeds from the uses specified in paragraph (c) of this section shall not exceed 3 percent in mineral supplements nor shall it exceed 0.06 percent of the total ration when present in feed or feed concentrates.

(e) When used in combination with technical white mineral oil for the uses described in paragraph (c) of this section, the total quantity of combined 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.

### § 573.760 Poloxalene.

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

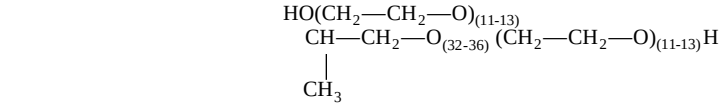
(a) The additive consists of polyoxypropylene-polyoxyethylene glycol nonionic block polymer meeting the following specifications:

(1) Molecular weight range: 2,850–3,150.

(2) Hydroxyl number: 35.7–39.4.

(3) Cloud point (10 percent solution): 42 °C–46 °C.

(4) Structural formula:



(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:

$0.9 \pm 0.1 \times 0.8 \pm 0.1 \times 1.2 \pm 0.1$

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

[41 FR 38652, Sept. 10, 1976, as amended at 54 FR 18282, 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 calf-milk 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.

### § 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 | 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 (h) 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 as provided in paragraph (c) of this section, as a controlled-release sodium selenite bolus as provided in paragraph (f) of this section, as selenium yeast as provided in paragraph (g) of this section, or as selenomethionine hydroxy analogue as provided in paragraph (h) of this section.

(c) Selenium, as sodium selenite or sodium selenate, 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.

(4) The additive, as sodium selenite or sodium selenate, 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 sheep or beef cattle from a premix containing no more than 4.5 grams of added selenium per pound.

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

(d) 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.

(e) 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.''

(f) 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.''

(g) Selenium yeast is a dried, nonviable 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 (d) and (e) of this section.

(h) Selenomethionine hydroxy analogue [R,S–2-hydroxy-4-methylselenobutanoic acid (CAS 873660–49–2)] is manufactured by the reaction of elemental selenium with methyllithium to form a methylseleno salt, which is then reacted with R,S–2-hydroxybutyrolactone to form a salt of 2-hydroxy-4-methylselenobutanoic acid. After acidification and purification, the additive consists of not less than 39.5 percent total selenium by weight with a selenomethionine hydroxy analogue content of not less than 98 percent of total selenium. The total organic selenium content of the additive is not less than 99 percent of total selenium.

(1) The selenomethionine hydroxy analogue meets the following specifications:

(i) Arsenic, not more than 2 parts per million (ppm);

(ii) Cadmium, not more than 1 ppm;

(iii) Lead, not more than 1 ppm; and

(iv) Mercury, not more than 1 ppm.

(2) Selenium, as selenomethionine hydroxy analogue, 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 ppm.

(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.

(3) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling of selenomethionine hydroxy analogue in its packaged form shall contain:

(i) The name, selenomethionine hydroxy analogue;

(ii) Minimum and maximum guarantees for a total selenium content of not less than 2.08 percent (weight/weight) and not more than 2.24 percent;

(iii) Minimum guarantee for selenomethionine hydroxy analogue content of not less than 5.2 percent;

(iv) The following statement, ''Storage Conditions: Selenomethionine hydroxy analogue must be stored in a closed package at temperatures not higher than 20 °C (68 °F).''; and

(v) An expiration date not to exceed 1 year from the date of manufacture.

(4) The additive, as selenomethionine hydroxy analogue, 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.

(5) Usage of this additive must conform to the requirements of paragraphs (d) and (e) 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; 84 FR 7993, Mar. 6, 2019; 86 FR 37036, July 14, 2021]

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 as an anticaking agent, antifoaming agent, carrier, and/or grinding aid in animal feed, including ingredients, intermediate premixes, premixes, supplements, concentrates, and complete feed.

(c) To ensure safe use of the additive, silicon dioxide is to be used in an amount not to exceed that reasonably required to accomplish its intended effect, and silicon dioxide from all sources cannot exceed 2 percent by weight of the complete feed.

(d) To ensure safe use of the additive, the label and labeling of the additive and ingredients, intermediate premixes, premixes, supplements, concentrates, and complete feed containing the additive shall meet the requirements of the Federal Food, Drug, and Cosmetic Act, including part 501 of this chapter.

(e) To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling of the additive and ingredients, intermediate premixes, premixes, supplements, and concentrates containing the additive shall have:

(1) A statement of the concentration of the additive.

(2) A statement that silicon dioxide from all sources cannot exceed 2 percent by weight of the complete feed.

[41 FR 38652, Sept. 10, 1976, as amended at 83 FR 8930, Mar. 2, 2018; 84 FR 7993, Mar. 6, 2019; 85 FR 33539, June 2, 2020]

### § 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:

(1) In calf milk replacers at a maximum use level of 0.1 percent, as fed.

(2) In liquid feed supplements for ruminant animals at a maximum use level of 0.25 percent (5 pounds per ton).

(c) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to other information required by the act, the name of the additive.

(2) The label or labeling of the additive container shall bear adequate directions for use.

[49 FR 44630, Nov. 8, 1984]

### § 573.1020 Yellow prussiate of soda.

Yellow prussiate of soda (sodium ferrocyanide decahydrate: $Na_4Fe(Cn)_6°\text{-}10H_2O$) may be safely used as an anticaking agent in salt for animal consumption at a level not to exceed 13 parts per million. The additive contains a minimum of 99.0 percent by weight of sodium ferrocyanide decahydrate.

[41 FR 38657, Sept. 10, 1976; 41 FR 48100, Nov. 2, 1976]