

§ 172.770

(b) The additive meets the following specifications:

- Acid number 50–150.
- Hydroxyl number 15–50.
- Succinated ester content 45–75 percent.

(c) The additive is used or intended for use as an emulsifier in or with shortenings and edible oils intended for use in cakes, cake mixes, fillings, icings, pastries, and toppings, in accordance with good manufacturing practice.

§ 172.770 Ethylene oxide polymer.

The polymer of ethylene oxide may be safely used as a foam stabilizer in fermented malt beverages in accordance with the following conditions.

(a) It is the polymer of ethylene oxide having a minimum viscosity of 1,500 centipoises in a 1 percent aqueous solution at 25 °C.

(b) It is used at a level not to exceed 300 parts per million by weight of the fermented malt beverage.

(c) The label of the additive bears directions for use to insure compliance with paragraph (b) of this section.

§ 172.775 Methacrylic acid-divinylbenzene copolymer.

Methacrylic acid-divinylbenzene copolymer may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is produced by the polymerization of methacrylic acid and divinylbenzene. The divinylbenzene functions as a cross-linking agent and constitutes a minimum of 4 percent of the polymer.

(b) Aqueous extractives from the additive do not exceed 2 percent (dry basis) after 24 hours at 25 °C.

(c) The additive is used as a carrier of vitamin B₁₂ in foods for special dietary use.

§ 172.780 Acacia (gum arabic).

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

(a) Acacia (gum arabic) is the dried gummy exudate from stems and branches of trees of various species of the genus *Acacia*, family Leguminosae.

(b) The ingredient meets the specifications of the “Food Chemicals

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Codex,” 5th Ed. (2004), pp. 210 and 211, 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 National Academies Press, 500 Fifth St. NW., Washington, DC 20001 (Internet address: <http://www.nap.edu>). Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 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.

(c) The ingredient is used as a thickener, emulsifier, or stabilizer in alcoholic beverages at a use level not to exceed 20 percent in the final beverage.

[70 FR 8034, Feb. 17, 2005]

§ 172.785 *Listeria*-specific bacteriophage preparation.

The additive may be safely used as an antimicrobial agent specific for *Listeria monocytogenes* (*L. monocytogenes*) in accordance with the following conditions:

(a) *Identity.* (1) The additive consists of a mixture of equal proportions of six different individually purified lytic-type (lacking lysogenic activity) bacteriophages (phages) specific against *L. monocytogenes*.

(2) Each phage is deposited at, and assigned an identifying code by, a scientifically-recognized culture collection center, and is made available to FDA upon request.

(3) The additive is produced from one or more cell cultures of *L. monocytogenes* in a safe and suitable nutrient medium.

(b) *Specifications.*(1) The additive achieves a positive lytic result (OD₆₀₀ ≤ 0.06) when tested against any of the following *L. monocytogenes* isolates available from American Type Culture Collection (ATCC): ATCC 35152 (serogroup 1/2a), ATCC 19118 (serogroup 4b), and

ATCC 15313 (serogroup 1/2b). The analytical method for determining the potency of the additive entitled "Determination of Potency of LMP-102™," dated October 9, 2003, and printed by Intralytix, Inc., 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 a copy from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, 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.

(2) The mean phage titer of each monophage in the additive is 1×10^9 plaque forming units (PFU)/ml. The analytical method for determining phage titer entitled "Method to Determine Lytic Activity/Phage Titer," dated November 6, 2001, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

(3) The phages present in the preparation must not contain a functional portion of any of the toxin-encoding sequences described in 40 CFR 725.421(d). No sequences derived from genes encoding bacterial 16S ribosomal RNA are present in the complete genomic sequence of the phages.

(4) *L. monocytogenes* toxin, listeriolysin O (LLO), is not greater than 5 hemolytic units (HU)/ml. The analytical method for determining LLO entitled "Quantitation of Listeriolysin O Levels in LMP-102™," dated September 27, 2004, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

(5) The additive is negative for *L. monocytogenes*. The modified version of

the U.S. Department of Agriculture's method for determining *L. monocytogenes* entitled "LMP-102™ *Listeria monocytogenes* Sterility Testing," dated May 24, 2004, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

(6) The additive is negative for gram-positive and gram-negative bacteria capable of growing in commonly used microbiological media (e.g., Luria-Bertani (LB) medium), including *Escherichia coli*, *Salmonella* species and coagulase-positive *Staphylococci*, as determined by the "Method to Determine Microbial Contamination," dated July 11, 2003, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

(7) Total organic carbon (TOC) is less than or equal to 36 mg/kg. The analytical method for determining TOC entitled "Determination of Total Organic Carbon by Automated Analyzer," dated March 30, 2001, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

(c) *Conditions of use.* The additive is used in accordance with current good manufacturing practice to control *L. monocytogenes* by direct application to meat and poultry products that comply with the ready-to-eat definition in 9 CFR 430.1. Current good manufacturing practice is consistent with direct spray application of the additive at a rate of approximately 1 mL of the additive per 500 cm² product surface area.

[71 FR 47731, Aug. 18, 2006]

Subpart I—Multipurpose Additives

§ 172.800 Acesulfame potassium.

Acesulfame potassium (CAS Reg. No. 55589-62-3), also known as acesulfame K, may be safely used as a general-purpose sweetener and flavor enhancer in foods generally, except in meat and poultry, in accordance with current good manufacturing practice and in an amount not to exceed that reasonably required to accomplish the intended technical effect in foods for which