Food and Drug Administration, HHS

(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 Codex, 8th ed. (2012), p. 516, 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 United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address: http://www.usp.org). Copies may be examined at the Food and Drug Administration’s Main Library, 10903 New Hampshire Ave., Bldg. 2, 3d Floor, Silver Spring, MD 20993, 301–796–2039, 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/ibr-locations.html.

(c) The ingredient is used in food in accordance with good manufacturing practices under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

<table>
<thead>
<tr>
<th>Food (as served)</th>
<th>Food (as served)</th>
<th>Percent</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beverages, alcoholic</td>
<td>Breakfast cereals, § 170.3(n)(4) of this chapter</td>
<td>20.0</td>
<td>Thickener, emulsifier, or stabilizer.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6.0</td>
<td>Dietary fiber; emulsifier and emulsifier salt; flavoring agent and adjuvant; formulation aid; processing aid; stabilizer and thickener; surface-finishing agent; texturizer.</td>
</tr>
<tr>
<td>Cakes, brownies, pastries, biscuits, muffins, and cookies.</td>
<td>Grain-based bars (e.g., breakfast bars, granola bars, rice cereal bars), soups and soup mixes, § 170.3(n)(40) of this chapter, except for soups and soup mixes containing meat or poultry that are subject to regulation by the U.S. Department of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act.</td>
<td>2.5</td>
<td>Do.</td>
</tr>
<tr>
<td>Grain-based bars (e.g., breakfast bars, granola bars, rice cereal bars).</td>
<td>35.0</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td>Soups and soup mixes, § 170.3(n)(40) of this chapter, except for soups and soup mixes containing meat or poultry that are subject to regulation by the U.S. Department of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act.</td>
<td>2.5</td>
<td>Do.</td>
<td></td>
</tr>
<tr>
<td>Food categories listed in § 184.1330 of this chapter, except for meat, poultry, and foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act preclude the use of acacia.</td>
<td>Levels prescribed in § 184.1330 of this chapter.</td>
<td>Dietary fiber.</td>
<td></td>
</tr>
<tr>
<td>Food categories listed in § 184.1330 of this chapter, except for meat, poultry, and foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act preclude the use of acacia.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


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.

(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-
§ 172.800

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 \(1 \times 10^9\) 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.


(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 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]