



# U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH



[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [A-Z Index](#)

[Questions?](#)



[510\(k\)](#) | [Registration](#) | [Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)

[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [Recalls](#) | [Guidance](#) | [Standards](#)

[New Search](#)

[Help](#) | [More About 21CFR](#)

[Code of Federal Regulations]  
[Title 21, Volume 1]  
[Revised as of April 1, 2006]  
[CITE: 21CFR73.85]

## TITLE 21--FOOD AND DRUGS

### CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### SUBCHAPTER A--GENERAL

#### [PART 73 -- LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION](#)

Subpart A--Foods

Sec. 73.85 Caramel.

(a) *Identity.* (1) The color additive caramel is the dark-brown liquid or solid material resulting from the carefully controlled heat treatment of the following food-grade carbohydrates:

Dextrose.

Invert sugar.

Lactose.

Malt sirup.

Molasses.

Starch hydrolysates and fractions thereof.

Sucrose.

(2) The food-grade acids, alkalis, and salts listed in this subparagraph may be employed to assist caramelization, in amounts consistent with good manufacturing practice.

(i) Acids:

Acetic acid.

Citric acid.

Phosphoric acid.

Sulfuric acid.

Sulfurous acid.

(ii) Alkalis:

Ammonium hydroxide.

Calcium hydroxide U.S.P.

Potassium hydroxide.

Sodium hydroxide.

(iii) Salts: Ammonium, sodium, or potassium carbonate, bicarbonate, phosphate (including dibasic phosphate and monobasic phosphate), sulfate, and sulfite.

(3) Polyglycerol esters of fatty acids, identified in 172.854 of this chapter, may be used as antifoaming agents in amounts not greater than that required to produce the intended effect.

produce the intended effect.

(4) Color additive mixtures for food use made with caramel may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

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

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 0.1 part per million.

(c) *Uses and restrictions.* Caramel may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

Database Updated April 1, 2006

---

[CDRH Home Page](#) | [CDRH A-Z Index](#) | [Contact CDRH](#) | [Accessibility](#) | [Disclaimer](#)  
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [HHS Home Page](#)

Center for Devices and Radiological Health / CDRH