

§ 172.130

Food	Limitation (parts per million)	Use
French dressing	75	Do.
Mayonnaise	75	Do.
Salad dressing	75	Do.
Sandwich spread	100	Do.
Sauces	75	Do.

(c) To assure safe use of the additive:

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

(2) The label or labeling of the additive container shall bear adequate use directions to provide a final food product that complies with the limitations provided in paragraph (b) of this section.

(d) In the standardized foods listed in paragraph (b) of this section, the additives are used only in compliance with the applicable standards of identity for such foods.

[42 FR 14491, Mar. 15, 1977, as amended at 48 FR 10815, Mar. 15, 1983; 58 FR 52222, Oct. 7, 1993; 60 FR 33710, June 29, 1995]

§ 172.130 Dehydroacetic acid.

The food additive dehydroacetic acid and/or its sodium salt may be safely used in accordance with the following prescribed conditions:

(a) The food additive meets the following specifications:

Dehydroacetic acid: Melting point, 109 °C–111 °C; assay, minimum 98 percent (dry basis).
Sodium salt of dehydroacetic acid: Assay, minimum 98 percent (dry basis).

(b) It is used or intended for use as a preservative for cut or peeled squash, and is so used that no more than 65 parts per million expressed as dehydroacetic acid remains in or on the prepared squash.

(c) The label or labeling of any package of the additive intended for use in food shall bear adequate directions for use to insure compliance with this section.

§ 172.133 Dimethyl dicarbonate.

Dimethyl dicarbonate (CAS Reg. No. 4525-33-1) may be safely used in food in accordance with the following prescribed conditions:

21 CFR Ch. I (4-1-98 Edition)

(a) The additive meets the following specifications:

(1) The additive has a purity of not less than 99.8 percent as determined by the following titration method:

PRINCIPLES OF METHOD

Dimethyl dicarbonate (DMDC) is mixed with excess diisobutylamine with which it reacts quantitatively. The excess amine is backtitrated with acid.

APPARATUS

- 250-milliliter (mL) Beaker
- 100-mL Graduated cylinder
- 25-mL Pipette
- 10-mL Burette (automatic, eg., Metrohm burette)
- Stirrer
- Device for potentiometric titration
- Reference electrode
- Glass electrode

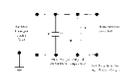
REAGENTS

- Acetone, analytical-grade
- Solution of 1 N diisobutylamine in chlorobenzene, distilled
- 1 N Acetic Acid

PROCEDURE

Accurately weigh in about 2 grams of the sample (W) and dissolve in 100 mL acetone. Add accurately 25 mL of the 1 N diisobutylamine solution by pipette and allow to stand for 5 minutes. Subsequently, titrate the reaction mixture potentiometrically with 1 N hydrochloric acid (consumption=*a* mL) while stirring. For determining the blank consumption, carry out the analysis without a sample (consumption=*b* mL).

CALCULATION



NOTE: For adding the diisobutylamine solution, always use the same pipette and wait for a further three drops to fall when the flow has stopped.

(2) The additive contains not more than 2,000 ppm (0.2 percent) dimethyl carbonate as determined by a method entitled "Gas Chromatography Method for Dimethyl Carbonate Impurity in Dimethyl Dicarbonate," which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), 200 C Street SW., Washington, DC 20204, or available for inspection at the Office of

the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

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

(1) Inhibitor of yeast in wine, dealcoholized wine, and low alcohol wine, under normal circumstances of bottling where the viable yeast count has been reduced to 500 per milliliter or less by current good manufacturing practices such as flash pasteurization or filtration. The additive may be added to wine, dealcoholized wine, or low alcohol wine in an amount not to exceed 200 parts per million (ppm).

(2) Inhibitor of yeast in ready-to-drink teas, under normal circumstances of bottling or canning where the viable yeast count has been reduced to 500 per milliliter or less by current good manufacturing practices such as heat treatment, sterile filtration, or both. The additive may be added to teas in an amount not to exceed 250 ppm.

(3) Inhibitor of yeast in carbonated or noncarbonated, nonjuice-containing (less than or equal to 1 percent juice), flavored or unflavored beverages containing added electrolytes (5–20 milliequivalents (meq)/liter sodium ion (Na+) and 3–7 meq/liter potassium ion (K+)). The additive may be added to the beverage in an amount not to exceed 250 ppm.

(4) Inhibitor of yeast in carbonated, dilute beverages containing juice, fruit flavor, or both, with juice content not to exceed 50 percent. The additive may be added to the beverage in an amount not to exceed 250 ppm.

(c) To ensure the safe use of the food additive, the label of the package containing the additive shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The name of the additive “dimethyl dicarbonate.”

(2) Directions to provide that not more than 200 ppm of dimethyl dicarbonate will be added to the wine, dealcoholized wine, or low alcohol wine and not more than 250 ppm of dimethyl dicarbonate will be added to the ready-to-drink tea or to the beverages de-

scribed in parts (b)(3) and (b)(4) of this section.

[53 FR 41329, Oct. 21, 1988, as amended at 58 FR 6091, Jan. 26, 1993; 59 FR 5319, Feb. 4, 1994; 61 FR 14245, Apr. 1, 1996; 61 FR 26788, May 29, 1996]

§ 172.135 Disodium EDTA.

The food additive disodium EDTA (disodium ethylenediaminetetraacetate) may be safely used in designated foods for the purposes and in accordance with the following prescribed conditions:

(a) The additive contains a minimum of 99 percent disodium ethylenediaminetetraacetate dihydrate (C₁₀H₁₄O₈N₂Na₂·2H₂O).

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

(1) Alone, in the following foods at not to exceed the levels prescribed, calculated as anhydrous calcium disodium EDTA:

Food	Limitation (parts per million)	Use
Aqueous multivitamin preparations.	150	With iron salts as a stabilizer for vitamin B ¹² in liquid multivitamin preparations.
Canned black-eyed peas	145	Promote color retention.
Canned cooked chickpeas ..	165	Do.
Canned kidney beans	165	Preservative.
Canned strawberry pie filling	500	Promote color retention.
Cooked sausage	36	As a cure accelerator with sodium ascorbate or ascorbic acid.
Dressings, nonstandardized	75	Preservative.
French dressing	75	Do.
Frozen white potatoes including cut potatoes.	100	Promote color retention.
Gefilte fish balls or patties in packing medium.	150	Inhibit discoloration.
Mayonnaise	75	Preservative.
Ready-to-eat cereal products containing dried bananas.	² 315	Promote color retention.
Salad dressing	75	Preservative.
Sandwich spread	100	Do.
Sauces	75	Do.

¹ Based on total weight of finished product including packing medium.

² In dried banana component of cereal product.

(2) With calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate; calcium disodium (ethylenedinitrilo) tetraacetate), in the following foods at not to exceed, in