§ 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:

(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 Graduate 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

$$\frac{(b-a)\times 13.4}{W} = \%\ \text{DMDC}$$

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,'' whichis 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 a microbial control agent in the following beverages under normal circumstances of bottling, canning, or other forms of final packaging, where the viable microbial load has been reduced to 500 microorganisms per milliliter or less by current good manufacturing practices such as heat treatment, filtration, or other technologies prior to the use of dimethyl dicarbonate:

(1) In wine, dealcoholized wine, and low alcohol wine in an amount not to exceed 200 parts per million.

(2) In ready-to-drink teas in an amount not to exceed 250 parts per million. unflavored beverages containing added electrolytes (5–20 milliequivalents/liter sodium ion (Na+) and 3–7 milliequivalents/liter potassium ion (K+)) in an amount not to exceed 250 parts per million.

(4) In carbonated, dilute beverages containing juice, fruit flavor, or both, with juice content not to exceed 50 percent, in an amount not to exceed 250 parts per million.

(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) The intended use of the additive.

(3) Adequate directions for use to ensure compliance with 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; 66 FR 13653, Mar. 7, 2001]

§ 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 ($C_{10}H_{14}O_8N_2Na_2 \cdot 2H_2O$).

(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 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.	[1] 50	Inhibit discoloration.
Legumes (all cooked canned, other than black-eyed peas).	165	Promote color retention.
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 combination, the levels prescribed, calculated as anhydrous $C_{10}H_{12}O_8N_2CaNa_2$:

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

(3) Alone, as a sequestrant in the nonnutritive sweeteners that are listed in § 180.37 of this chapter and that, in addition, are designed for aqueous solution: *Provided,* That the amount of the additive, calculated as anhydrous calcium disodium EDTA, does not exceed 0.1 percent by weight of the dry nonnutritive sweetener.

(c) To assure the 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 paragraphs (b) (1) and (2) 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 65 FR 48379, Aug. 8, 2000]

§ 172.140 Ethoxyquin.

(a) Ethoxyquin (1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline) may be safely used as an antioxidant for preservation of color in the production of chili powder, paprika, and ground chili at levels not in excess of 100 parts per million.

(b) In order to provide for the safe use of the additive in feed prepared in accordance with §§ 573.380 and 573.400 of this chapter, tolerances are established for residues of ethoxyquin in or on edible products of animals as follows:

5 parts per million in or on the uncooked fat of meat from animals except poultry.
3 parts per million in or on the uncooked liver and fat of poultry.
0.5 part per million in or on the uncooked muscle meat of animals.
0.5 part per million in poultry eggs.
Zero in milk.

§ 172.145 Heptylparaben.

(a) The food additive heptylparaben is the chemical *n*-heptyl *p*-hydroxybenzoate.

(b) It may be safely used to inhibit microbiological spoilage in accordance with the following prescribed conditions: