

(2) *Permitted combinations.* It may be used in accordance with the provisions of this section in the combinations provided, as follows:

(i) Bambermycins in accordance with § 558.95.

(ii) Roxarsone in accordance with § 558.530.

[41 FR 11005, Mar. 15, 1976, as amended at 42 FR 18618, Apr. 8, 1977; 42 FR 20817, Apr. 22, 1977; 42 FR 36995, July 19, 1977; 51 FR 7401, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 55 FR 8461, Mar. 8, 1990; 57 FR 8403, Mar. 10, 1992; 57 FR 8578, Mar. 11, 1992; 61 FR 35957, July 9, 1996; 63 FR 38750, July 20, 1998]

PART 564 [RESERVED]

PART 570—FOOD ADDITIVES

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AUTHORITY: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

SOURCE: 41 FR 38644, Sept. 10, 1976, unless otherwise noted.

Subpart A—General Provisions

§ 570.3 Definitions.

(a) *Secretary* means the Secretary of Health and Human Services.

(b) *Department* means the Department of Health and Human Services.

(c) *Commissioner* means the Commissioner of Food and Drugs.

(d) As used in this part, the term *act* means the Federal Food, Drug, and Cosmetic Act approved June 25, 1936 (52 Stat. 1040 *et seq.*, as amended; 21 U.S.C. 301–392).

(e) *Food additives* includes all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. *Affecting the characteristics of food* does not include such physical effects, as protecting contents of packages, preserving shape, and preventing moisture loss. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive. A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive.

(f) *Common use in food* means a substantial history of consumption of a substance by a significant number of animals in the United States.

(g) The word *substance* in the definition of the term *food additive* includes a food or feed or a component of a food or feed consisting of one or more ingredients.

(h) *Scientific procedures* include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance.

(i) *Safe* or *safety* means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of