

**§ 80.39**

that the person requesting certification may use such color additive for the purpose of coloring a food, drug, or cosmetic.

**§ 80.39 Records of distribution.**

(a) The person to whom a certificate is issued shall keep complete records showing the disposal of all the color additive from the batch covered by such certificate. Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee acting on behalf of the Secretary of Health and Human Services, such person, at all reasonable hours until at least 2 years after disposal of all such color additive, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such color additive on hand and otherwise to check the correctness of such records.

(b) The records required to be kept by paragraph (a) of this section shall show:

(1) Each quantity used by such person from such batch and the date and kind of such use.

(2) The date and quantity of each shipment or delivery from such batch, and the name and post-office address of the person to whom such shipment or delivery was made.

(c) The records required to be kept by paragraph (a) of this section shall be kept separately from all other records.

**PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS**

Sec.

- 81.1 Provisional lists of color additives.
- 81.10 Termination of provisional listings of color additives.
- 81.30 Cancellation of certificates.
- 81.32 Limitation of certificates.

AUTHORITY: 21 U.S.C. 371, 379e, 379e note.

**§ 81.1 Provisional lists of color additives.**

The Commissioner of Food and Drugs finds that the following lists of color additives are provisionally listed under

**21 CFR Ch. I (4-1-03 Edition)**

section 203(b) of the Color Additive Amendments of 1960 (sec. 203(b), 74 Stat. 405 (21 U.S.C. 379e note)). Except for color additives for which petitions have been filed, progress reports are required by January 1, 1968, and at 6-month intervals thereafter. Specifications for color additives listed in paragraphs (a), (b), and (c) of this section appear in the respective designated sections. The listing of color additives in this section is not to be construed as a listing for surgical suture use unless color additive petitions have been submitted for such use or the Commissioner has been notified of studies underway to establish the safety of the color additive for such use. The color additives listed in paragraphs (a), (b), and (c) of this section may not be used in products which are intended to be used in the area of the eye. The color additives listed in paragraphs (a), (b), and (c) of this section are provisionally listed until the closing dates set forth therein.

(a) *Color additives previously and presently subject to certification and provisionally listed for food, drug, and cosmetic use.*

Color additive	Closing date		Restrictions
	Food use	Drug and cosmetic use	
Lakes (FD&C) (sec. 82.51 of this chapter).			

(b) *Color additives previously and presently subject to certification and provisionally listed for drug and cosmetic use.*

	Closing date	Restrictions
Lakes (D&C) (Sec. 82.2051 of this chapter).		

(c) *Color additives previously and presently subject to certification and provisionally listed for use in externally applied drugs and cosmetics.*

	Closing date	Restrictions
Lakes (Ext. D&C) (sec. 82.105(1) of this chapter)		

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