§ 82.2050  General.

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of this part, for use in externally applied drugs and cosmetics, if such batch conforms to the requirements of §82.5 and to the specifications set forth in this subpart for such color.

§ 82.2051  Lakes (Ext. D&C).

(a)(1) General. Any lake made by extending on a substratum of alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or on any combination of two or more of these (i) one of the straight colors hereinbefore listed in this subpart, which color is a salt in which is combined the basic radical sodium, potassium, barium, or calcium; or (ii) a salt prepared from one of the straight colors hereinbefore listed in this subpart by combining such color with the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

(2) Specifications.
Ether extracts, not more than 0.5 percent.
Soluble chlorides and sulfates (as sodium salts), not more than 3.0 percent.
Intermediates, not more than 0.2 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:
(1) The listed name of the color from which the lake is prepared;
(2) The name of the basic radical combined in such color; and
(3) The word “Lake.” (For example, the name of a lake prepared by extending the color Ext. D&C Yellow No. 2 upon a substratum is “Ext. D&C Yellow No. 2—Calcium Lake,” and a lake prepared by extending the barium salt prepared from Ext. D&C Red No. 2 upon the substratum is “Ext. D&C Red No. 2—Barium Lake.”)

§ 82.2707a  Ext. D&C Yellow No. 7.

The color additive Ext. D&C Yellow No. 7 shall conform in identity with specifications to the requirements of §74.1707(a)(1) and (b) of this chapter. Ext. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.