

Subpart B—Drugs

§ 73.1001 Diluents in color additive mixtures for drug use exempt from certification.

The following diluents may be safely used in color additive mixtures that are exempt from certification and which are to be used for coloring drugs, subject to the condition that each straight color in the mixture has been exempted from certification or, if not so exempted, is from a batch that has previously been certified and has not

changed in composition since certification. Such listing of diluents is not to be construed as superseding any of the other requirements of the Federal Food, Drug, and Cosmetic Act with respect to drugs, including new drugs. If a definition and specification for a particular diluent is not set forth in this subpart, the material shall be of a purity consistent with its intended use.

(a) *Ingested drugs*—(1) *General use.* Diluents listed in § 73.1(a) and the following:

Substances	Definitions and specifications	Restrictions
Alcohol, specially denatured	As set forth in 26 CFR, pt. 212	As set forth in 26 CFR, pt. 211.
Cetyl alcohol	As set forth in N.F. XI.	
Isopropyl alcohol	In color coatings for pharmaceutical forms, no residue.
Polyoxyethylene (20) sorbitan monostearate (Polysorbate 60).	As set forth in sec. 172.836 of this chapter.	
Polyoxyethylene (20) sorbitan tristearate (Polysorbate 65).	As set forth in sec. 172.838 of this chapter.	
Polysorbate 80	As set forth in sec. 172.840 of this chapter.	
Polyvinyl-pyrrolidone	As set forth in sec. 173.55 of this chapter.	
Sorbitan monooleate.		
Sorbitan monostearate	As set forth in sec. 172.842 of this chapter.	
Sorbitan trioleate.		

(2) *Special use; inks for branding pharmaceutical forms.* Items listed in paragraph (a)(1) of this section, § 73.1(b)(1)(i), and the following:

Ethyl lactate
Polyoxyethylene sorbitan monolaurate (20)

(b) *Externally applied drugs.* Diluents listed in paragraph (a)(1) of this section and the following:

Substances	Definitions and specifications
Benzyl alcohol	As set forth in N.F. XI.
Ethyl cellulose	As set forth in § 172.868 of this chapter.
Hydroxyethyl cellulose.	
Hydroxypropyl cellulose	As set forth in § 172.870 of this chapter.

§ 73.1010 Alumina (dried aluminum hydroxide).

(a) *Identity.* (1) The color additive alumina (dried aluminum hydroxide) is a white, odorless, tasteless, amorphous powder consisting essentially of aluminum hydroxide (Al₂O₃·XH₂O).

(2) Color additive mixtures for drug use made with alumina (dried alu-

minum hydroxide) may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Alumina (dried aluminum hydroxide) shall conform to the following specifications:

Acidity or alkalinity: Agitate 1 gram of the color additive with 25 milliliters of water and filter. The filtrate shall be neutral to litmus paper.

Matter insoluble in dilute hydrochloric acid, not more than 0.5 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

Mercury (as Hg), not more than 1 part per million.

Aluminum oxide (Al₂O₃), not less than 50 percent.

(c) *Uses and restrictions.* Alumina (dried aluminum hydroxide) may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) *Labeling requirements.* The label of the color additive and of any mixtures