Food and Drug Administration, HHS

§ 73.1200 Synthetic iron oxide.

(a) Identity. (1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(2) Color additive mixtures for drug use made with synthetic iron oxide may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring drugs.

(b) Specifications. Synthetic iron oxide shall conform to the following specifications, all on an “as is” basis:

- Arsenic (as As), not more than 3 parts per million.
- Lead (as Pb), not more than 10 parts per million.
- Mercury (as Hg), not more than 3 parts per million.

(c) Uses and restrictions. The color additive synthetic iron oxide may be safely used to color ingested or topically applied drugs generally subject to the restriction that if the color additive is used in drugs ingested by man the amount consumed in accordance with labeled or prescribed dosages shall not exceed 5 milligrams, calculated as elemental iron, per day.

(d) Labeling requirements. The label of the color additive and any mixtures intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of §70.25 of this chapter.

(e) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

42 FR 52394, Sept. 30, 1977

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