\section*{§ 73.1991 Zinc oxide.}

\subsection*{§ 73.1991 Identity.} (1) The color additive zinc oxide is a white or yellow-white amorphous powder manufactured by the French process (described as the indirect process whereby zinc metal isolated from the zinc-containing ore is vaporized and then oxidized). It is principally composed of Zn.

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

\subsection*{§ 73.1991 Specifications.} Zinc oxide shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

- Zinc oxide (as ZnO), not less than 99 percent.
- Loss on ignition at 800 °C, not more than 1 percent.
- Cadmium (as Cd), not more than 15 parts per million.
- Mercury (as Hg), not more than 1 part per million.
- Arsenic (as As), not more than 3 parts per million.
- Lead (as Pb), not more than 20 parts per million.

\subsection*{§ 73.1991 Uses and restrictions.} The color additive zinc oxide may be safely used for coloring externally applied drugs, including those used in the area of the eye, in amounts consistent with good manufacturing practice.

\subsection*{§ 73.1991 Labeling.} The color additive and any mixtures prepared therefrom 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.

\subsection*{§ 73.1991 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 the certification requirements of section 721(c) of the act.

[42 FR 37537, July 22, 1977]

\section*{Subpart C—Cosmetics}

\section*{§ 73.2085 Caramel.}

\subsection*{§ 73.2085 Identity and specifications.} The color additive caramel shall conform in identity and specifications to the requirements of §73.85(a)(1), (2), and (3) and (b).

\subsection*{§ 73.2085 Uses and restrictions.} Caramel is safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

\subsection*{§ 73.2085 Labeling requirements.} The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of §70.25 of this chapter.

\subsection*{§ 73.2085 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 the certification requirement of section 721(c) of the act.

[46 FR 38501, July 28, 1981]

\section*{§ 73.2087 Carmine.}

\subsection*{§ 73.2087 Identity and specifications.} The color additive carmine shall conform in identity and specifications to the requirements of §73.100(a)(2) and (b)(2).

\subsection*{§ 73.2087 Use and restrictions.} Carmine may be safely used in cosmetics generally, including cosmetics intended for use in...