Colorcon®

Regulatory Information Sheet

International Regulatory Status of D&C Yellow #10 and Quinoline Yellow (E104) Dye and Lake

D&C Yellow #10 and Quinoline Yellow (E104) are both sometimes referred to as quinoline yellow which has created significant confusion when companies are formulating global products. Although similar in appearance, these colors are two different chemicals and cannot be interchanged. Unfortunately, due to the regulatory issues listed below, these differences create challenges when developing products that are to be marketed globally. This usually results in the need for multiple versions of a product which are formulated to meet regulatory requirements in specific geographic markets.

United States

21 CFR (Part 74) lists the approved color as D&C Yellow #10. The specifications are listed in 21 CFR (Section 74.1710) which requires that the dye contain not less than 75% of the monosulfonated component and not more than 15% of the disulfonated component. Currently, D&C Yellow #10 is approved in the U.S. for use in drugs and cosmetics but is not approved for food uses.

Issue: This material is **not** acceptable for use in foods or drugs in Europe due to a difference in the specifications of the monosulfonated and disulfonated components of the dye.

European Union

EC Regulation 1333/2008 permits the use of Quinoline Yellow (E104) and requires that the material contain not less than 80% of the disulfonated component and not more than 15% of the monosulfonated component. Quinoline Yellow (E104) is approved in Europe for use in food and drug products.

Therefore, by definition you cannot have a material that meets both the U.S. and the European specifications.

Specifications			
	Monosulfonated Component	Disulfonated Component	Regulation
D&C Yellow #10	<NLT 75% allowed	>NMT 15% allowed	FDA 21 CFR (74.1710)
Quinoline Yellow (E104)	>NMT 15% allowed	<NLT 80% allowed	EC Regulation 1333/2008

Japan

D&C Yellow #10 and Quinoline Yellow (E104) are NOT approved for use in foods or drugs in Japan at this time. There has not been a precedent of use of either color in a drug product which has been approved by

the Ministry of Health, Labor and Welfare (MHLW). This does not preclude the potential for use; however, significant justification data would have to be submitted to support the inclusion of these colors. This may be difficult and delay product approvals.

Other Countries

In other countries, acceptance of these colors varies. It is important that the specific regulations of the target countries be evaluated before making a formulation decision. A customized, product specific regulatory assessment based on your individual needs can be requested from Colorcon's Global Regulatory Affairs group via our on-line request system or by contacting your local Colorcon representative directly.

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