



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 much controversy when companies are trying to formulate global products. 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 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 Directive 94/36/EC lists the approved color as Quinoline Yellow (E104). The specific purity requirements are listed in EC Directive 95/45/EC which 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 drugs.

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

Specifications for Use in Drugs*			
	Monosulfonated Component	Disulfonated Component	Compendia
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 Directive 94/36/EC

*Neither D&C Yellow #10 nor Quinoline Yellow are listed in either regions for use in foods.

Japan

D&C Yellow #10 and Quinoline Yellow (E104) are **NOT** approved for use in foods or drugs 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

Some countries such as Canada, Chile, Indonesia, Pakistan, etc. accept either color. Both are known to be used in Australia. Others countries such as China, Brazil, Mexico, etc. do not allow for the use of D&C Yellow #10 or Quinoline Yellow (E104). It is important that the specific regulations of the target countries be evaluated before making a formulation decision. Colorcon's International Pharmaceutical Color Regulations Database Reports can be helpful in providing initial guidance. These guides are available upon request.

Future Initiatives

Trade organizations such as the International Association of Color Manufacturers (IACM) are discussing The differences in acceptability of D&C Yellow #10 vs. Quinoline Yellow (E104) around the world and it's impact on the industry's ability to manufacture a globally acceptable products with international regulators to see if there could be modifications of the regulations in the future. However, at this time, there are no proposals or petitions in place which will impact the specification situation.

IACM has petitioned the FDA to broaden the acceptability of D&C Yellow #10 for food use in the U.S. and to make it an FD&C color. This process will probably take several years to complete.

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