

(i) At a level not to exceed 0.2 percent by weight of the suture material for coloring polyglactin 910 (glycolic-lactic acid polyester) synthetic absorbable sutures for use in general and ophthalmic surgery; and

(ii) At a level not to exceed 0.3 percent by weight of the suture material for coloring polydioxanone synthetic absorbable sutures for use in general and ophthalmic surgery.

(iii) At a level not to exceed 0.25 percent by weight of the suture material for coloring poliglecaprone 25 (ϵ -caprolactone/glycolide copolymer) synthetic absorbable sutures for use in general surgery.

(iv) At a level not to exceed 0.1 percent by weight of the suture material for coloring poly(ϵ -caprolactone) absorbable sutures for use in general surgery.

(3) The color additive, D&C Violet No. 2, may be safely used for coloring polymethylmethacrylate intraocular lens haptics at a level not to exceed 0.2 percent by weight of the haptic material.

(4) Authorization for these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical devices in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Violet No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[52 FR 19722, May 27, 1987, as amended at 55 FR 18868, May 7, 1990; 58 FR 60109, Nov. 15, 1993; 59 FR 11720, Mar. 14, 1994]

§ 74.3710 D&C Yellow No. 10.

(a) *Identity.* The color additive D&C Yellow No. 10 shall conform to the identity requirements of § 74.1710(a).

(b) *Specifications.* The color additive D&C Yellow No. 10 for use in contact lenses shall conform to the specifications of § 74.1710(b).

(c) *Uses and restrictions.* (1) The color additive D&C Yellow No. 10 may be used for coloring contact lenses in amounts not to exceed the minimum

reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[52 FR 28690, Aug. 3, 1987]

APPENDIX A TO PART 74—THE PROCEDURE FOR DETERMINING ETHER SOLUBLE MATERIAL IN D&C RED NOS. 6 AND 7

The dye is dissolved in glacial acetic and 8 N hydrochloric acids (1.33:1) and extracted with diethyl ether. Sulfonated moieties, including the color additive, are discarded in subsequent aqueous extractions of the ether. Carboxylated moieties are removed from the ether by extraction with 2% (w/w) NaOH. The ether is evaporated to near dryness, ethanol (95%) is added, and the solution is analyzed spectrophotometrically in the visible range. The absorbance at each wavelength must not exceed 150% of the absorbance similarly obtained for D&C Red No. 6 Lot AA5169.

APPARATUS

(A) Spectrophotometer (Cary 118 or equivalent).

(B) Separatory funnels—one 1000 mL and one 500 mL.

REAGENTS

NOTE: Use *distilled* water when water is required.

(A) Glacial Acetic Acid (ACS grade).

(B) Diethyl ether (Anhydrous)—Note and follow safety precautions on container.

(C) 8 N HCl—Pour 165 mL H₂O into a 500 mL graduate. Place the graduate in hood, then add HCl conc. to bring to volume. Carefully pour this solution into a 500 mL Erlenmeyer flask, Stopper and shake. Label the flask.

(D) 2% (w/w) NaOH—Pour ca 190 mL H₂O into a 250 mL mixing graduate. Add 8 g. (5.23 mL) of 50% (w/w) NaOH, bring to 200 mL volume with water, stopper and mix. Pour this solution into a glass bottle, label and stopper with a polytetrafluoroethylene top.

(E) Ethanol (95%).

PROCEDURE

Weigh a 250 mL beaker to tenths of a mg and add 100 mg of dye. Record weight to tenths of a mg.

NOTE: The following work must be performed in the hood.

Add 75 mL of 8 N HCl and 100 mL of glacial acetic acid to the beaker and stir.

Place the beaker on a hot plate and heat with stirring, until all of the dye is in solution.

Remove the beaker from the hot plate, cover with a watch glass and allow to cool to room temperature (1-2 hrs).

When the dye solution is at room temperature, transfer the solution to a 1000 mL separatory funnel.

Rinse the beaker three times with 50 mL portions of H₂O, transferring each rinse to the 1000 mL funnel.

Add 150 mL of ether to the funnel, stopper and shake for 10 seconds, then invert funnel and open stopcock to remove gas buildup.

Shake the funnel for one minute, opening the stopcock a few times while the funnel is inverted to remove gas buildup. (Use this shake procedure throughout method.)

Allow the funnel to stand until the layers have separated.

Transfer the bottom (aqueous) layer to a 500 mL separatory funnel, add 100 mL of ether, stopper and shake for one minute.

When the layers have separated, drain off the bottom layer into a waste beaker.

Pour the ether layer in the 500 mL separatory funnel into the 1000 mL separatory funnel.

Rinse the 500 mL sep. funnel with 100 mL H₂O, then transfer it to the 1000 mL sep. funnel, stopper and shake for one minute.

When the layers have separated, drain off the bottom aqueous layer into the waste beaker.

Rinse the 500 mL funnel at least three times (total) and repeat the 100 mL water washes until no color is present in the aqueous layer. Discard the bottom aqueous layer to the waste beaker after each separation.

Shake the ether layer twice more with 100 mL portions of H₂O, discarding the bottom aqueous layer after each separation.

Remove the unsulfonated subsidiary color from the ether by shaking the ether layer for

one minute with 20 mL of 2% (w/w) NaOH. *Appropriately label* a 100 mL beaker. After the layers separate, drain the aqueous alkaline layer into the beaker and save for the determination of 3-hydroxy-4-[(4-methylphenyl)azo]-2-naphthalenecarboxylic acid, sodium salt.

If there is any color left in the ether, shake for one minute with another 20 mL portion of 2% (w/w) NaOH. After the layers have separated, drain off the aqueous alkaline layer into the 100 mL beaker.

If color remains in the ether layer, repeat the above step for a total of three washes of the ether with 2% (w/w) NaOH. Note: Three washes is usually sufficient to remove the unsulfonated subsidiary.

With the stopper removed, *gently* swirl the ether layer in the sep. funnel twice to separate the remaining aqueous base. Drain this into the 100 mL beaker.

Appropriately label a 250 mL beaker. *Pour* the ether layer into the beaker. Allow the ether to evaporate to *near* dryness. Cool to room temperature. Add ca 8 mL ethanol (95%). Swirl beaker to mix contents. Quantitatively transfer to a 25 mL graduate using ethanol (95%) rinses. Add ethanol (95%) to bring volume to 15 mL.

SPECTROPHOTOMETRIC ANALYSIS

Spectrophotometer Parameters:

Scan Range: 400-700 nm

Scan: 50 nm/in; 5.0 nm/sec.

Absorbance Range: 0-1 AUFS

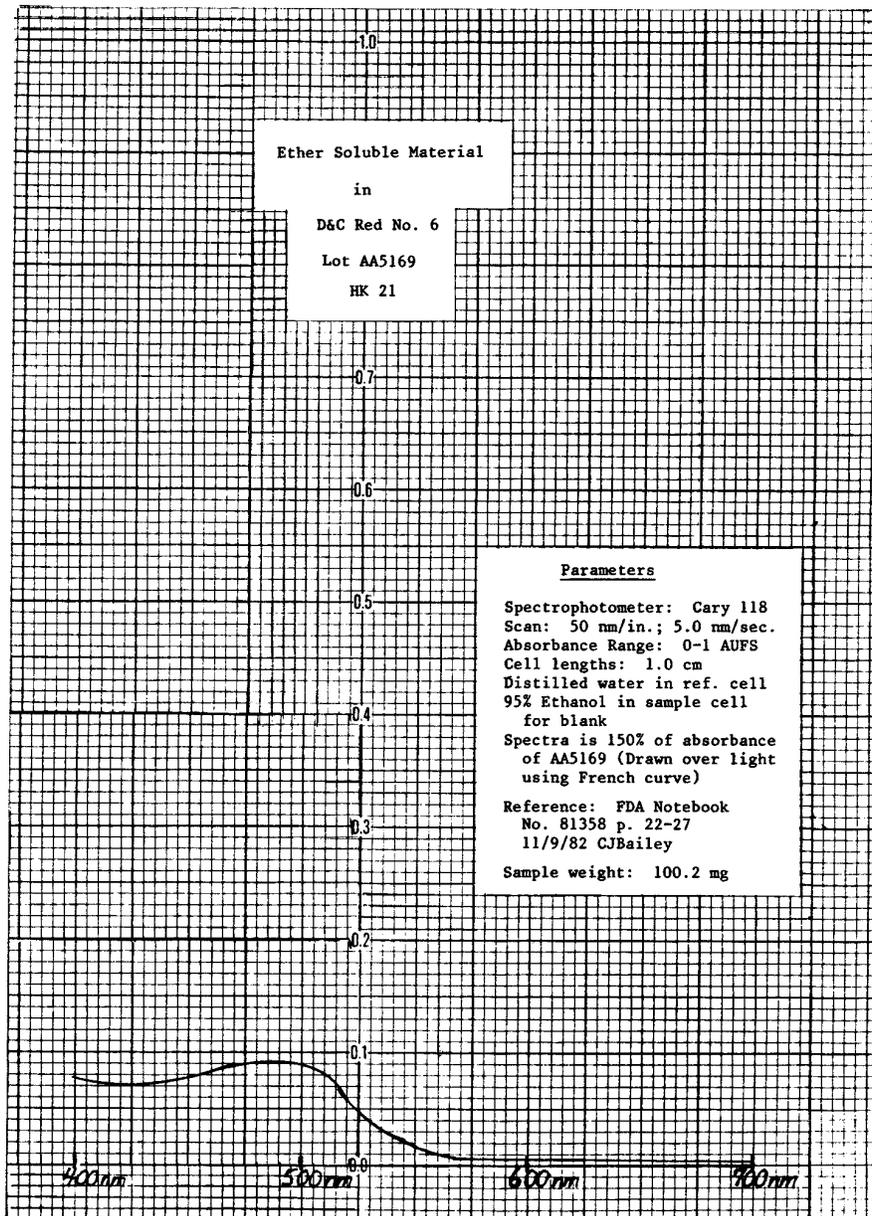
Cell length: 1 cm (Note: Reference and Sample cells)

(1) Record the visible spectrum of a blank. Fill the reference cell with distilled water and the sample cell with ethanol (95%).

(2) Rinse the sample cell with 2-3 mL of the ether soluble material (in ethanol solution); then fill the cell. Record the visible spectrum of the ether soluble material.

(3) Compare the spectra obtained to the spectra attached. The attached spectra represents 150% of the absorbance at each wavelength for similarly analyzed D&C Red No. 6 Lot AA5169.

The spectra of the current sample must not exceed the attached spectra at any wavelength in order to *pass test*.



[47 FR 57688, Dec. 28, 1982; 48 FR 3946, Jan. 28, 1983; 48 FR 7438, Feb. 22, 1983; 48 FR 10811, Mar. 15, 1983]

PART 80—COLOR ADDITIVE CERTIFICATION

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AUTHORITY: 21 U.S.C. 371, 379e.

SOURCE: 42 FR 15662, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 80.10 Fees for certification services.

(a) *Fees for straight colors including lakes.* The fee for the services provided by the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(1) and (j)(2) shall be 30 cents per pound of the batch covered by such requests, but no such fee shall be less than \$192.

(b) *Fees for repacks of certified color additives and color additive mixtures.* The fees for the services provided under the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(3) and (j)(4) shall be:

(1) 100 pounds or less—\$30.

(2) Over 100 pounds but not over 1,000 pounds—\$30 plus 6 cents for each pound over 100 pounds.

(3) Over 1,000 pounds—\$84 plus 2 cents for each pound over 1,000 pounds.

(c) *Advance deposits.* Any person regularly requesting certification services may deposit funds in advance of requests as prepayment of fees required by this section.

(d) *Method of payment.* All deposits and fees required by this section shall be paid by money order, bank draft, or certified check, drawn to the order of the Food and Drug Administration, collectable at par at Washington, DC. All such deposits and fees shall be forwarded to the Center for Food Safety and Applied Nutrition (HFS-100), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, whereupon after making appropriate records thereof, they will be transmitted to the Treasurer of the United States for deposit to the special account "Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration."

(e) *Refunds from advance deposits.* Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except that no refund shall be made where the computed ratable amount for the elapsed period is less than \$5.00.

[42 FR 15662, Mar. 22, 1977, as amended at 47 FR 24692, June 8, 1982; 54 FR 24890, June 12, 1989; 59 FR 60899, Nov. 29, 1994; 61 FR 3572, Feb. 1, 1996; 61 FR 14479, Apr. 2, 1996]

Subpart B—Certification Procedures

§ 80.21 Request for certification.

A request for certification of a batch of color additive shall:

(a) Be addressed to the Commissioner of Food and Drugs.

(b) Be prepared in the manner set forth in paragraph (j) of this section.

(c) Be submitted in duplicate.

(d) Be signed by a responsible officer of the person requesting certification of the batch. In the case of a foreign manufacturer, the request for certification must be signed by a responsible officer of such firm, and, by his agent who resides in the United States.