

§ 21.64**27 CFR Ch. I (4-1-12 Edition)**

210. External pharmaceuticals, not U.S.P. or N.F.

450. Cleaning solutions (including household detergents).

(2) As a raw material:

530. Ethylamines.

540. Dyes and intermediates.

579. Other chemicals.

(3) Miscellaneous uses:

812. Product development and pilot plant uses (own use only).

§ 21.64 Formula No. 37.

(a) *Formula.* To every 100 gallons of alcohol add:

Forty-five fluid ounces of eucalyptol, N.F. XII, 30 avoirdupois ounces of thymol, N.F., and 20 avoirdupois ounces of menthol, U.S.P.

(b) *Authorized uses.* (1) As a solvent:

111. Hair and scalp preparations.

112. Bay rum.

113. Lotions and creams (hand, face, and body).

131. Dentifrices.

132. Mouth washes.

210. External pharmaceuticals, not U.S.P. or N.F.

244. Antiseptic solutions, U.S.P. or N.F.

410. Disinfectants, insecticides, fungicides, and other biocides.

430. Sterilizing and preserving solutions.

470. Theater sprays, incense, and room deodorants.

(2) Miscellaneous uses:

812. Product development and pilot plant uses (own use only).

§ 21.65 Formula No. 38-B.

(a) *Formula.* To every 100 gallons of alcohol add:

Ten pounds of any one, or a total of 10 pounds of two or more, of the oils and substances listed below:

Alpha terpineol

Anethole, N.F.

Anise oil, N.F.

Bay oil (myrcia oil), N.F. XI.

Benzaldehyde, N.F.

Bergamot oil, N.F. XI.

Bitter almond oil, N.F. X.

Camphor, U.S.P.

Cedar leaf oil, U.S.P. XIII.

Chlorothymol, N.F. XII.

Cinnamic aldehyde, N.F. IX.

Cinnamon oil, N.F.

Citronella oil, natural.

Clove oil, N.F.

Coal tar, U.S.P.

Eucalyptol, N.F. XII.

Eucalyptus oil, N.F.

Eugenol, U.S.P.

Guaiacol, N.F. X.

Lavender oil, N.F.

Menthol, U.S.P.

Methyl salicylate, N.F.

Mustard oil, volatile (allyl isothiocyanate), U.S.P. XII.

Peppermint oil, N.F.

Phenol, U.S.P.

Phenyl salicylate (salol), N.F. XI.

Pine oil, N.F. XII.

Pine needle oil, dwarf, N.F.

Rosemary oil, N.F. XII.

Safrole.

Sassafras oil, N.F. XI.

Spearmint oil, N.F.

Spearmint oil, terpeneless.

Spike lavender oil, natural.

Storax, U.S.P.

Thyme oil, N.F. XII.

Thymol, N.F.

Tolu balsam, U.S.P.

Turpentine oil, N.F. XI.

If it is shown that none of the above single denaturants or combinations can be used in the manufacture of a particular product, the user may submit an application to the appropriate TTB officer, requesting permission to use another essential oil or substance having denaturing properties satisfactory to the appropriate TTB officer. In such a case the user shall furnish the appropriate TTB officer, with specifications, assay methods, the name and address of the manufacturer, and an 8-ounce sample of the denaturant for analysis.

(b) *Authorized uses.* (1) As a solvent:

111. Hair and scalp preparations.

112. Bay rum.

113. Lotions and creams (hand, face, and body).

114. Deodorants (body).

121. Perfumes and perfume tinctures.

122. Toilet waters and colognes.

131. Dentifrices.

132. Mouth washes.

141. Shampoos.

142. Soap and bath preparations.

210. External pharmaceuticals, not U.S.P. or N.F.

243. Liniments, U.S.P. or N.F.

244. Antiseptic solutions, U.S.P. or N.F.

249. Miscellaneous external pharmaceuticals, U.S.P. or N.F.

349. Miscellaneous drug processing (including manufacture of pills).

410. Disinfectants, insecticides, fungicides, and other biocides.

430. Sterilizing and preserving solutions.

470. Theater sprays, incense, and room deodorants.

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(2) Miscellaneous uses:

812. Product development and pilot plant uses (own use only).

[T.D. ATF-133, 48 FR 24673, June 2, 1983, as amended by T.D. ATF-442, 66 FR 12854, Mar. 1, 2001]

§ 21.66 Formula No. 38-C.

(a) *Formula.* To every 100 gallons of alcohol add:

Ten pounds of menthol, U.S.P., and 1.25 gallons of formaldehyde solution, U.S.P.

(b) *Authorized uses.* (1) As a solvent:

- 131. Dentifrices.
- 132. Mouth washes.

(2) Miscellaneous uses:

812. Product development and pilot plant uses (own use only).

§ 21.67 Formula No. 38-D.

(a) *Formula.* To every 100 gallons of alcohol add:

Two and one-half pounds of menthol, U.S.P., and 2.5 gallons of formaldehyde solution, U.S.P.

(b) *Authorized uses.* (1) As a solvent:

- 131. Dentifrices.
- 132. Mouth washes.

(2) Miscellaneous uses:

812. Product development and pilot plant uses (own use only).

§ 21.68 Formula No. 38-F.

(a) *Formula.* To every 100 gallons of alcohol add:

(1) Six pounds of either boric acid, N.F., or Polysorbate 80, N.F.; 1½ pounds of thymol, N.F.; 1½ pounds of chlorothymol, N.F. XII; and 1½ pounds of menthol, U.S.P.; or

(2) A total of at least 3 pounds of any two or more denaturing materials listed under Formula No. 38-B, plus sufficient boric acid, N.F., or Polysorbate 80, N.F., to total 10 pounds of denaturant; or

(3) Seven pounds of zinc chloride, U.S.P., 2.6 fluid ounces of hydrochloric acid, N.F., and a total of 3 pounds of any two or more of the denaturing materials listed under Formula No. 38-B.

(b) *Authorized uses.* (1) As a solvent:

- 132. Mouth washes.
- 210. External pharmaceuticals, not U.S.P. or N.F.
- 244. Antiseptic solutions, U.S.P. or N.F.

(2) Miscellaneous uses:

812. Product development and pilot plant uses (own use only).

§ 21.69 Formula No. 39.

(a) *Formula.* To every 100 gallons of alcohol add:

Nine pounds of sodium salicylate, U.S.P., or salicylic acid, U.S.P.; 1.25 gallons of fluid extract of quassia, N.F. VII; and ¼ gallon of *tert*-butyl alcohol.

(b) *Authorized uses.* (1) As a solvent:

- 111. Hair and scalp preparations.
- 112. Bay rum.
- 113. Lotions and creams (hand, face, and body).
- 121. Perfume and perfume tinctures.
- 122. Toilet waters and colognes.

(2) Miscellaneous uses:

812. Product development and pilot plant uses (own use only).

§ 21.70 Formula No. 39-A.

(a) *Formula.* To every 100 gallons of alcohol add:

Sixty avoirdupois ounces of any one of the following alkaloids or salts together with ¼ gallon of *tert*-butyl alcohol:

- Quinine, N.F. X.
- Quinine bisulfate, N.F. XI.
- Quinine dihydrochloride, N.F. XI.
- Cinchonidine.
- Cinchonidine sulfate, N.F. IX.

(b) *Authorized uses.* (1) As a solvent:

- 111. Hair and scalp preparations.
- 122. Toilet waters and colognes.
- 141. Shampoos.

(2) Miscellaneous uses:

812. Product development and pilot plant uses (own use only).

§ 21.71 Formula No. 39-B.

(a) *Formula.* To every 100 gallons of alcohol add:

Two and one-half gallons of diethyl phthalate and ¼ gallon of *tert*-butyl alcohol.

(b) *Authorized uses.* (1) As a solvent:

- 111. Hair and scalp preparations.
- 112. Bay rum.
- 113. Lotions and creams (hand, face, and body).
- 114. Deodorants (body).
- 121. Perfumes and perfume tinctures.
- 122. Toilet waters and colognes.
- 141. Shampoos.
- 142. Soap and bath preparations.
- 210. External pharmaceuticals, not U.S.P. or N.F.