

## **1513-0011**

### **Sec. 5273. - Sale, use, and recovery of denatured distilled spirits**

#### **(a) Use of specially denatured distilled spirits**

Any person using specially denatured distilled spirits in the manufacture of articles shall file such formulas and statements of process, submit such samples, and comply with such other requirements, as the Secretary shall by regulations prescribe, and no person shall use specially denatured distilled spirits in the manufacture or production of any article until approval of the article, formula, and process has been obtained from the Secretary.

#### **(b) Internal medicinal preparations and flavoring extracts**

##### **(1) Manufacture**

No person shall use denatured distilled spirits in the manufacture of medicinal preparations or flavoring extracts for internal human use where any of the spirits remains in the finished product.

##### **(2) Sale**

No person shall sell or offer for sale for internal human use any medicinal preparations or flavoring extracts manufactured from denatured distilled spirits where any of the spirits remains in the finished product.

#### **(c) Recovery of spirits for reuse in manufacturing**

Manufacturers employing processes in which denatured distilled spirits withdrawn under section 5214(a)(1) are expressed, evaporated, or otherwise removed, from the articles manufactured shall be permitted to recover such distilled spirits and to have such distilled spirits restored to a condition suitable solely for reuse in manufacturing processes under such regulations as the Secretary may prescribe.

#### **(d) Prohibited withdrawal or sale**

No person shall withdraw or sell denatured distilled spirits, or sell any article containing denatured distilled spirits for beverage purposes.

#### **(e) Cross references**

(1) For penalty and forfeiture for unlawful use or concealment of denatured distilled spirits, see section 5607.

(2) For applicability of all provisions of law relating to distilled spirits that are not denatured, including those requiring payment of tax, to denatured distilled spirits or articles produced, withdrawn, sold, transported, or used in violation of law or regulations, see section 5001(a)(6). [\[1\]](#)

(3) For definition of "articles", see section 5002(a)(14)

### **§ 20.91 Formula.**

(a) Each article made with specially denatured spirits shall be made in accordance with (1) an approved formula, Form 5150.19, or (2) an approved general-use formula prescribed in this subpart, approved by the appropriate TTB officer as an alternate method, or published as a TTB Ruling in the TTB Bulletin. The manufacturer shall file Form 5150.19, along with the sample(s) required by § 20.92, and obtain an approved formula before manufacturing the article.

(b) An article made in accordance with a formula on Form 1479-A approved under previous regulations in part 211 of this chapter will be considered to comply with the requirements of this subpart.

(c) Any person who has approved formulas or statements of process, Form 1479-A or Form 5150.19, which have been discontinued or have become obsolete, may submit these formulas or statements of process to the appropriate TTB officer for cancellation.

### **§ 20.92 Samples.**

(a) For each formula submitted in accordance with § 20.91 covering a toilet preparation made with S.D.A. Formula No. 39-C and containing an essential oil, the manufacturer shall submit a 0.5-ounce sample of the essential oil used in the article. The appropriate TTB officer may also require the manufacturer to submit a sample of any ingredient which is not adequately described in the formula.

(b) For each formula submitted in accordance with § 20.91, the appropriate TTB officer may require the manufacturer to submit a 4-ounce sample of the finished article.

(c) The appropriate TTB officer may, at any time, require submission of samples of:

(1) Any ingredient used in the manufacture of an article, or;

(2) Any article.

[T.D. TTB- 199, 50 FR 1962, Mar. 6, 1985, as amended by T.D. TTB-435, 66 FR 5474, Jan. 19, 2001]

**§ 20.93 Changes to formulas.**

(a) *General.* Except as provided in paragraph (b) of this section, any change of ingredients or quantities of ingredients listed in an approved formula shall constitute a different article for which a different approved formula is required by § 20.91.

(b) *Exceptions.* A different approved formula is not required for the following --

(1) A change from an ingredient identified in the formula by a brand name to the same quantity of a chemically identical ingredient acquired under a different brand name, or

(2) A change of an ingredient which is a coloring material.

**§ 20.94 Statement of process.**

(a) Manufacturers shall submit a statement of process on Form 5150.19, in accordance with paragraph (b) of this section, covering the following activities:

(1) If specially denatured spirits are used for laboratory or mechanical purposes, other than use of S.D.A. Formula No. 3-A, 3-C, or 30 for laboratory or mechanical purposes not in the development of a product;

(2) If specially denatured spirits are used in a manufacturing process in which none of the specially denatured spirits remains in the finished product;

(3) If specially denatured spirits, completely denatured alcohol, or articles are used in a manufacturing process and are to be recovered; or

(4) If recovered denatured spirits are to be re-denatured.

(b) The manufacturer shall submit a separate Form 5150.19 for each activity described in paragraph (a) of this section describing the process completely.

(1) If specially denatured spirits are used for laboratory or mechanical purposes, other than use of S.D.A. Formula No. 3-A, 3-C, or 30 for laboratory or mechanical purposes not in the development of a product, the Form 5150.19 shall identify the formula number of specially denatured spirits, a description of the laboratory or mechanical use, and the approximate annual quantity to be used.

(2) If the Form 5150.19 is submitted covering activities described in paragraphs (a)(2), (a)(3), or (a)(4) of this section, the Form 5150.19 shall also contain the following information:

(i) Flow diagrams shall be submitted with the Form 5150.19 clearly depicting the equipment in its relative operating sequence, with essential connecting pipelines and valves. All major equipment shall be identified as to its use. The direction of flow through the pipelines shall be indicated in the flow diagram. The flow diagram, shall be accompanied by a written description of the flow of materials through the system.

(ii) The statement of process shall describe the chemical composition of the recovered spirits. The statement of process shall be accompanied by a statement of the intended use of the recovered spirits.

### **§ 20.100 General.**

(a) In addition to the limitations in this part, and if necessary to protect the revenue or public safety, the appropriate TTB officer, when approving Form 5150.19 may:

(1) Specify on the Form 5150.19 the size of containers in which any article may be sold;

(2) Specify the maximum quantity that may be sold to any person at one time; or

(3) Restrict the sale of an article to a specific class of vendee and for a specific use.

(b) Approval by the appropriate TTB officer of formulas, samples, or statements of process means only that they meet the standards of the Alcohol and Tobacco Tax and Trade Bureau. The approval does not require the issuance of a permit under subpart D of this part to withdraw and use specially denatured spirits in those formulas, articles, or statements of process.

[T.D. TTB- 199, 50 FR 1962, Mar. 6, 1985, as amended by T.D. TTB-435, 66 FR 5474, Jan. 19, 2001]

### **§ 20.101 Drafting formulas.**

(a) In preparing Form 5150.19, the manufacturer shall, for each ingredient containing ethyl alcohol, identify --

(1) The percent alcohol by volume of the ingredient, if known, and

(2) The supplier's name and serial number or approval date of the supplier's approved formula covering the manufacture of the ingredient.

(b) In preparing Form 5150.19, manufacturers may --

(1) Identify ingredients by generic names rather than brand names, and

(2) Identify quantities of ingredients used in ranges rather than in finite quantities.

(c) If ranges of ingredients are used, as authorized by paragraph (b)(2) of this section --

(1) The lower range shall not be zero for any ingredient, and

(2) The range for usage of specially denatured spirits shall not exceed  $\pm 5\%$ .