TTB Disclaimer

Notice:

• This information is being presented to help the public to understand and comply with the laws and regulations that the Alcohol and Tobacco Tax and Trade Bureau (TTB) administers.

• It is not intended to establish any new, or change any existing, definitions, interpretations, standards, or procedures regarding those laws and regulations.

• In addition, this presentation may be made obsolete by changes in laws and regulations.

• Please consult the applicable laws and regulations for the most current requirements.
Common Formula Questions

• What is a formula?
• Why is a formula required?
• When is a formula required?
• How is a formula submitted?
What is a Formula?

• A formula is a recipe.
• It must indicate a Total Yield, or Batch Size.
• It must have a quantitative list of ingredients.
• It must include a description of how the product is produced.

Measurement

Yield Summary

Ingredients List
List all ingredients to be used in formulating a batch of the product. Please enter the ingredients in production order.

Draft Lemon Pale Ale
90.0 - 99.0% ABV, 4.6% - 6.6% PaO

Flavor Group: Natural Mango Flavor
1.2 - 1.8 L

Flavor Group: Natural Raspberry Mint Flavor
4.0 - 5.6 L

Flavor Group: Natural and Artificial Pineapple Flavor
3.5 - 5.6 L

Flavor Group: Natural and Artificial Banan Coffee Flavor
1.0 - 2.6 L

Flavor Group: Natural and Artificial Tropical Fruit Flavor
2.8 - 5.0 L

Flavor Group: Natural Blackberry Blueberry Flavor
1.0 - 2.6 L

FD&C Blue #1
40.0 - 48.0 mL

Titanium Dioxide
2.0 - 4.9 g

Sodium Benzoate
60.0 - 80.0 g

Caramel
100.0 - 110.0 mL

Method of Manufacture
Describe in sequence each step used to produce the product.

Method of Manufacture Document:

Add Attachment
Why is a Formula required?

• Regulation requirement - 27 CFR 25.55-58

• Formula review finds a “home” for a product and assigns it a particular classification.

• A Statement of Composition describes the product in a generic fashion, example “Malt Beverage with Natural Flavors and Certified Colors.”
When are Formulas required?

- TTB Industry Circular 2007-4
- A formula is required if:
  - Flavors with alcohol are added
  - Compound flavors are added
  - Colors are added
  - Artificial sweeteners are added
  - Agricultural products not listed in TTB Ruling 2015-1 are used

For unique processes:
- The beverage is frozen and ice crystals may be removed (i.e., ice beer)
When are Formulas required?

• A formula is required if (cont.):
  – The alcohol is less than 0.5% or the alcohol is completely removed (i.e., non-alcoholic malt beverage or alcohol free malt beverage)
  – A TTB employee requests it
  – A small percentage will require lab review
• A formula is not required for:
  – Barrel aging
  – Addition of an agricultural product listed under TTB Ruling 2015-1 (e.g., cherries)
Are Formulas required for all products?

- **TTB Ruling 2015-1**
  

- **TTB Industry Circular 2007-4**
  
Malt Beverage Formula Tool

Which Alcohol Beverages Require Formula Approval?

**Beer and Malt Beverage Products**

*Beer*, under the Internal Revenue Code of 1986 (IRC) and the TTB regulations, means beer, ale, porter, stout and other similar fermented beverages (including sake and similar products) containing one-half of one percent or more of alcohol by volume, brewed or produced from malt, wholly or in part, or from substitutes for malt. Only rice, grain of any kind, bran, glucose, sugar, and molasses are substitutes for malt.

*Malt beverage*, under the Federal Alcohol Administration Act (FAA Act) and the TTB regulations, means a beverage, which may be alcoholic, non-alcoholic, or alcohol-free, made by the alcoholic fermentation of an infusion or decoction, or combination of both, in potable brewing water, of:

- malted barley and hops (or their parts or products) AND, with or without:
  - other malted cereals;
  - unmalted or prepared cereals;
  - other carbohydrates (or products prepared thereof);
  - carbon dioxide; and
  - other wholesome products suitable for human food consumption.

**NOTE:** In order for a brewery product to fall within the definition of a “malt beverage” under the FAA Act, it must be a fermented beverage made from both malted barley and hops, or their parts, or their products. A fermented beverage that qualifies as a “beer” under the IRC but that is made without both malted barley and hops is not a malt beverage under the FAA Act. For more information see TTB Ruling 2008-3.

Tell us about your product or browse the lists of beers and malt beverage products that require formula approval or formula approval and laboratory sample analysis.

**Source**

- [ ] Domestic
- [ ] Imported

CONTINUE
How to Submit a Formula

- Electronic Submission - *Formulas Online*
- Paper Submissions - use *TTB F 5100.51* and mail to TTB.
Common Return Reasons

• Please upload a specification sheet or an image of the label clearly showing the list of ingredients for the following item(s). Specification sheets are typically available from the ingredient manufacturer.

• Please complete and attach a Beverage Alcohol Limited Components Calculation sheet for the purchased flavors and/or blenders you are using. This will aid us in our review of the use rates for any limited ingredients (e.g., vanillin and propylene glycol) contained in these ingredients.

• Please upload a Flavor Ingredient Data (FID) Sheet for each compounded flavor specified in your ingredients list. You can obtain FID sheets from the flavor manufacturer.

• The method of manufacture (MoM) should be a detailed, step-by-step guide that describes how the product is made and includes all ingredients. Please revise your MoM accordingly.
Reasons Continued

- *This malt beverage product does not require formula review nor sample analysis because it is composed of exempt ingredients or processes. You may proceed to Labeling.*

- *A malt beverage must contain hops or their parts. Please clarify if hops are being added.*

- *To help us evaluate your formula, in the Submitter Remarks section below, please provide the information that is being requested regarding the following ingredient(s)*

- *Please provide a copy of the GRAS Notification and number (Generally Recognized as Safe) for the ingredient. GRAS notifications are issued by the U.S. Food and Drug Administration (FDA).*

- *Quantities were not provided for all ingredients. Please update the list of ingredients to specify the amount of each.*
What TTB Looks For

• Correct designation (Class and Type) – Is the base produced according to the stated standard?
• Colors, flavors, and artificial sweeteners.
• Flavors and Flavor Ingredient Data (FID) sheets.
• GRAS (generally recognized as safe) ingredients.
• Restricted and Prohibited Ingredients.
Helpful Hints

• Supply a quantitative list of ingredients.

• Provide a complete method of manufacture.

• Indicate at what stage flavors are added to the product.

• Flavor Ingredient Data Sheets (FIDS) should include a TTB number, a Flavor Product Number, and the TTB Approval status (Nonbeverage Lab Approval).

• Provide the common name and scientific name (genus and species) for any unusual herbal ingredients. Ensure that ingredients are GRAS (generally recognized as safe).
Flavors
Compounded Flavors

• Are classified as:
  • All natural
  • Natural and artificial containing not more than 0.1% artificial content topnote
  • Natural and artificial containing greater than 0.1% artificial content topnote
  • All artificial
  • Non-flavor: product is not flavor (e.g., Cloud Emulsion)
• Submitted to TTB Nonbeverage Lab for Review
• May contain colors
Flavor Ingredient Data Sheet (FIDS)

- Flavor Manufacturer supplies form to the Producer.
- FID based on exchange between Flavor Producer and TTB Non-beverage Laboratory.
- It lists concentration of Limited Ingredients in PPM.
- Any colors used in flavor.
- States alcohol content of flavor.
- This information, combined with the use rate, determines classification of flavor.
# Flavor Ingredient Datasheet

## Flavor Ingredient Data Sheet

### Flavor Producer Information
- **FTC Code**: 762/5356
- **Company Name**: [Redacted]
- **Address**: 123 Main St, Anytown, USA
- **City**: Anytown
- **State**: USA
- **Zip**: 12345
- **Phone**: (555) 123-4567
- **Fax**: (555) 789-0123

### Flavor Name
- **Flavor Name**: [Redacted]
- **TDS/Drink Mix Number**: [Redacted]
- **Alcohol Range by Volume**: [Redacted]
- **Flavor Product Number**: [Redacted]

### Classification
- **Category**: [Redacted]
- **N/A**: [Redacted]
- **Artificial**: [Redacted]
- **Non-Flavor**: [Redacted]

### Flavor Components

<table>
<thead>
<tr>
<th>Additive</th>
<th>TDS Limitation in Finished Product</th>
<th>Amount of Additive or Agent Present &amp; Flavor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Synthetic Vanilla</td>
<td>40.0 ppm</td>
<td>ppm</td>
</tr>
<tr>
<td>2. Ethyl Vanillin</td>
<td>10.0 ppm</td>
<td>ppm</td>
</tr>
<tr>
<td>3. Synthetic Vanilla</td>
<td>20.0 ppm</td>
<td>ppm</td>
</tr>
<tr>
<td>4. Ethyl Maltol</td>
<td>100.0 ppm</td>
<td>ppm</td>
</tr>
<tr>
<td>5. Ether Quinone</td>
<td>100.0 ppm</td>
<td>ppm</td>
</tr>
<tr>
<td>6. SVO</td>
<td>15.0 ppm</td>
<td>ppm</td>
</tr>
<tr>
<td>7. Sodium Benzoate</td>
<td>180.0 ppm</td>
<td>ppm</td>
</tr>
<tr>
<td>8. Ethan Alcohol</td>
<td>30000.0 ppm</td>
<td>ppm</td>
</tr>
<tr>
<td>9. Regal Rose</td>
<td>50000.0 ppm</td>
<td>ppm</td>
</tr>
<tr>
<td>10. BHA (0.5% Commercial Oil)</td>
<td>ppm</td>
<td>%</td>
</tr>
<tr>
<td>11. Acetic Acid</td>
<td>1500.0 ppm</td>
<td>ppm</td>
</tr>
<tr>
<td>12.</td>
<td>ppm</td>
<td>ppm</td>
</tr>
<tr>
<td>13.</td>
<td>ppm</td>
<td>ppm</td>
</tr>
<tr>
<td>14.</td>
<td>ppm</td>
<td>ppm</td>
</tr>
<tr>
<td>15. Total Vanillin</td>
<td>40.0 ppm</td>
<td>ppm</td>
</tr>
<tr>
<td>16. Total Malt</td>
<td>30.0 ppm</td>
<td>ppm</td>
</tr>
</tbody>
</table>

### Confidential Limited Ingredients Not Shown (CLS)
- **Check if contained in formula**: [Redacted]
- **Check if CLS was previously submitted**: [Redacted]

### Beverage Manufacturer/Importer
- **Name**: [Redacted]
- **Address**: [Redacted]
- **City**: [Redacted]
- **State**: [Redacted]
- **Zip**: [Redacted]
- **Phone**: [Redacted]
- **Fax**: [Redacted]

### Flavor Alcohol Manufacturer/Importer
- **Name**: [Redacted]
- **Address**: [Redacted]
- **City**: [Redacted]
- **State**: [Redacted]
- **Zip**: [Redacted]
- **Phone**: [Redacted]
- **Fax**: [Redacted]
## Flavor Ingredient Data Sheet

### Flavor Producer Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>TTB Co. Code</td>
<td>WLOVE</td>
</tr>
<tr>
<td>Company Name</td>
<td>We Love Flavors</td>
</tr>
<tr>
<td>Address</td>
<td>6000 Ammendale Rd</td>
</tr>
<tr>
<td></td>
<td>Beltville, MD 20705</td>
</tr>
<tr>
<td>Date</td>
<td>5/29/2014</td>
</tr>
<tr>
<td>Contact Person</td>
<td>Martha Washington</td>
</tr>
<tr>
<td>Phone</td>
<td>240-555-1212</td>
</tr>
<tr>
<td>Fax</td>
<td>240-5551213</td>
</tr>
</tbody>
</table>

### Flavor Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flavor Name</td>
<td>Nat. Chocolate WONF</td>
</tr>
<tr>
<td>TTB Drawback Number</td>
<td>1510</td>
</tr>
<tr>
<td>Alcohol Range by Volume</td>
<td>63.5 +/- 3.5%</td>
</tr>
<tr>
<td>Flavor Product Number</td>
<td>X1257</td>
</tr>
</tbody>
</table>

### Classification

- Natural [✓]
- N&A ≤ 0.1% Topnote [☐]
- N&A > 0.1% Topnote [☐]
- Artificial [☐]
- Non-Flavor [☐]

**Total Artificial Flavor Content:** 0 ppm (Excluding Synthetic Vanillin, Ethyl Vanillin, Synthetic Maltol, and Ethyl Maltol)
## Limited Ingredients Section

<table>
<thead>
<tr>
<th>Additive</th>
<th>TTB Limitation in Finished Product</th>
<th>Amount of Additive or Agent Present in Flavor</th>
<th>Maximum Use Rate</th>
<th>Beverage Label Information based of functionality</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Synthetic Vanillin</td>
<td>40.0 ppm</td>
<td>ppm</td>
<td>- %</td>
<td>1. FD&amp;C Yellow #5 □</td>
</tr>
<tr>
<td>2. Ethyl Vanillin</td>
<td>16.0 ppm</td>
<td>ppm</td>
<td>- %</td>
<td>2. FD&amp;C Yellow #6 □</td>
</tr>
<tr>
<td>3. Synthetic Maltol</td>
<td>250.0 ppm</td>
<td>ppm</td>
<td>- %</td>
<td>3. FD&amp;C Blue #1 □</td>
</tr>
<tr>
<td>4. Ethyl Maltol</td>
<td>100.0 ppm</td>
<td>ppm</td>
<td>- %</td>
<td>4. FD&amp;C Blue #2 □</td>
</tr>
<tr>
<td>5. Ester Gum</td>
<td>100.0 ppm</td>
<td>ppm</td>
<td>- %</td>
<td>5. FD&amp;C Green #3 □</td>
</tr>
<tr>
<td>6. BVO</td>
<td>15.0 ppm</td>
<td>ppm</td>
<td>- %</td>
<td>6. FD&amp;C Red #40 □</td>
</tr>
<tr>
<td>7. Sodium Benzoate</td>
<td>1000.0 ppm</td>
<td>ppm</td>
<td>- %</td>
<td>7. Grapeskin Extract □</td>
</tr>
<tr>
<td>8. Gum Arabic/Acacia</td>
<td>200000.0 ppm</td>
<td>ppm</td>
<td>- %</td>
<td>8. Caramel Color □</td>
</tr>
<tr>
<td>9. Propylene Glycol</td>
<td>50000.0 ppm</td>
<td>30,000 ppm</td>
<td>NO LIMIT %</td>
<td>9. Annatto □</td>
</tr>
<tr>
<td>10. BHA (&lt;0.5% Essential Oil)</td>
<td>ppm</td>
<td>check if contained</td>
<td>- %</td>
<td>10. Elderberry Extract □</td>
</tr>
<tr>
<td>11. Acetic Acid</td>
<td>1500.0 ppm</td>
<td>ppm</td>
<td>- %</td>
<td>11. Beet Extract □</td>
</tr>
<tr>
<td>12.</td>
<td>ppm</td>
<td>ppm</td>
<td>- %</td>
<td>12. Oak Extract □</td>
</tr>
<tr>
<td>14.</td>
<td>ppm</td>
<td>ppm</td>
<td>- %</td>
<td>14. □</td>
</tr>
<tr>
<td>15. Total Vanillin</td>
<td>40.0 ppm</td>
<td>ppm</td>
<td>- %</td>
<td></td>
</tr>
<tr>
<td>16. Total Maltol</td>
<td>250.0 ppm</td>
<td>ppm</td>
<td>- %</td>
<td></td>
</tr>
</tbody>
</table>
TTB Limited Ingredients

- TTB has 4 limited ingredients:
  - Synthetic maltol
  - Ethyl maltol
  - Synthetic vanillin
  - Ethyl vanillin

- If these limits are exceeded, the “natural flavor” will be treated as artificial flavor in the product.
Prohibited and Limited Ingredients

– FDA maintains a list of prohibited ingredients at 21 CFR part 189.
– Other non-prohibited ingredients may be used within limits.
  • [http://www.ttb.gov/ssd/limited_ingredients.html](http://www.ttb.gov/ssd/limited_ingredients.html)
– TTB does not approve formulas with directly added caffeine, vitamins, or minerals.
<table>
<thead>
<tr>
<th>Certified Colors – 21 CFR Part 74 Subpart A</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FD&amp;C Blue #1</strong></td>
</tr>
<tr>
<td><strong>FD&amp;C Blue #2</strong></td>
</tr>
<tr>
<td><strong>FD&amp;C Green #3</strong></td>
</tr>
<tr>
<td><strong>FD&amp;C Red #40</strong></td>
</tr>
<tr>
<td><strong>FD&amp;C Red #3</strong></td>
</tr>
<tr>
<td><strong>FD&amp;C Yellow #5</strong>*</td>
</tr>
<tr>
<td><strong>FD&amp;C Yellow #6</strong></td>
</tr>
</tbody>
</table>

*Requires specific declaration on labels for finished alcohol beverages.*
Non-Certified Colors 21 CFR part 73 subpart A

- Annatto Extract
- Dehydrated beets (beet powder)
- Canthaxanthin
- Caramel Color
- Carmine (Cochineal Extract)*
- Carrot oil
- β-Apo-8′-carotenal
- β-Carotene
- Fruit Juice
- Grape color extract
- Grapeskin Extract (Enocianina)

*Requires specific declaration on labels for finished alcohol beverages. This is a partial list, see 21 CFR part 73 for complete list.
FDA Requirements

- FDA has authority over food and ingredient safety
- Generally Recognized as Safe
  - Specifically recognized in the regulations under 21 CFR parts 170-186
  - FDA will treat as a food substance.
  - Traditional medicine / dietary supplements are not necessarily GRAS
- Importer/producer is responsible for proving that an ingredient is GRAS.
Treasury Decision 21

• Effective January, 2006 – See also 7.11
• If the final ABV is less than or equal to 6%, at least 51% of the alcohol in the final product must come from the malt base, no more than 49% of the alcohol in the final product can come from the flavor and other nonbeverage materials.
• If the final ABV is greater than 6%, no more than 1.5% of the volume of the malt beverage can consist of alcohol from flavors and other nonbeverage ingredients containing alcohol.
• An ABV statement must appear on the label if any alcohol in the malt beverage was derived from the added flavors. – 27 CFR 7.22(a)(5)
Regulations & Resources

- 27 CFR 7.10 – Meaning of terms
- 27 CFR 7.24(a) – Class and Type
- 27 CFR 25.11 – Meaning of terms
- 27 CFR 25.15 – Materials for the production of beer
- 27 CFR 25.55-58 – Formulas
- TTB Industry Circular 2007-4
- TTB Ruling 2008-3 – Classification of brewed products
- TTB Ruling 2015-1 – Ingredients and processes not subject to formula requirements
- Beverage Alcohol Manual (BAM) for Malt Beverages
Summary & Questions