

## Ingredients Statements

### Approved Ingredients Statements\*

Each [unit] contains: [established name] 000 mg.

Contains no preservatives.

### Design Guidelines for Ingredients Statements

**Font family** Helvetica Neue Std.

**Font weight** Light.

*If space constraints:* Light Condensed.

#### Font size

4–7 point suggested. Panel size dependent.  
Sunovion approval required for size below 4 point.

#### Relational size

All Descriptive Text must be the same size.

#### Placement

*Preferred:* Side panel within Descriptive Text block (see Preferred Order of Descriptive Text).

*Spacing between lines (leading):* When statements are longer than one line, baseline to baseline spacing between lines will be 110–120% of font size.

*Spacing between paragraphs (paragraph leading):* Baseline to baseline spacing between paragraphs will be 150–200% of font size.

*Alignment:* Left aligned.

#### Margins

Margins from all edges of label must be a minimum of 1/16" (1.5 mm; 4.5 points).

#### Color

*Light background color:* Black.

*Dark background color:* Reverse to white.  
Font weight should change to Medium.

#### Preferred Order of Descriptive Text

- 1) Ingredients Statements
- 2) Dosage Statements
- 3) Product Storage, Handling, and Use Statements
- 4) Temperature Storage Statements
- 5) Patient's Instructions for Use Statements
- 6) Warning Statements
- 7) Child Caution Statements

*Paragraph treatment:* Ingredients Statements, as well as each Descriptive Text category, should be a separate paragraph.

#### Reference

21 CFR Section 201.10. Drugs; statement of ingredients.

\*Other formulation ingredients may be needed.