



# Style Guide

08/2017

For use in the  
United States



# Labeling Guidelines

The contents in this style guide are based on 500 million or 1 billion CFU/day and contain suggested guidelines for labeling.

## Acceptable front of packaging claims

<p>These claims require the following disclaimer, which must be prominently displayed: <i>*As part of a balanced diet and healthy lifestyle.</i></p>	<ul style="list-style-type: none"> <li>• Probiotic cultures*</li> <li>• Supports the digestive system*</li> <li>• Supports digestive health*</li> <li>• Supports digestive functions*</li> <li>• Supports the immune system*</li> <li>• Supports immune health*</li> <li>• Supports immune function*</li> <li>• Supports protein utilization*</li> <li>• Enhances protein utilization*</li> </ul>	<p><i>Please note that probiotic claims are based on 500 million cfu/day of GadenenBC<sup>30</sup></i></p>
<p>This claim requires the following disclaimer: <i>**In an independent lab study of a simulated gastric environment with a pH of 2.0 for two hours, GadenenBC<sup>30</sup> cells were delivered 10X more effectively than common yogurt cultures.</i></p>	<ul style="list-style-type: none"> <li>• GadenenBC<sup>30</sup> survives 10X more effectively than yogurt cultures**</li> </ul>	<p><i>Please note that digestive health claims are based on 1 billion cfu/day of GadenenBC<sup>30</sup></i></p>
		<p><i>Please note that immune health claims are based on 500 million cfu/day of GadenenBC<sup>30</sup></i></p>
		<p><i>Please note that protein utilization claims are based on 1 billion cfu/day of GadenenBC<sup>30</sup></i></p>
		<p><i>Note: This claim refers to the ability of GadenenBC<sup>30</sup> cells to survive gastric transit and is NOT a cell count comparison</i></p>

**The above claims should reference the probiotic ingredient, not the finished product, on packaging.**

### Important

Gadenen reserves the right to review and approve the formatting of the usage of the GadenenBC<sup>30</sup> registered trademark and the logo. Final packaging, advertising and promotional material is the responsibility of the Licensee and should be reviewed by appropriate counsel to ensure compliance with the FTC, FDA, and other regulatory standards (including state laws).

## Acceptable Ingredient Labeling

Concentration	Description	Ingredient Listing
15 Billion CFU	Kosher Pareve	Maltodextrin, <i>Bacillus coagulans</i> GBI-30 6086 (contains soy)
15 Billion CFU	Kosher Pareve Allergen Free	Organic Inulin, <i>Bacillus coagulans</i> GBI-30 6086
9 Billion CFU	Kosher Pareve	Maltodextrin, Palm Oil, <i>Bacillus coagulans</i> GBI-30 6086 (contains soy)
9 Billion CFU	Kosher Pareve Allergen Free	Organic Inulin, Palm Oil, <i>Bacillus coagulans</i> GBI-30 6086
2 Billion CFU	Kosher Pareve	<i>Microcrystalline Cellulose</i> , <i>Bacillus coagulans</i> GBI-30 6086 (contains soy)
15 Billion CFU	Kosher Dairy	Skim Milk Powder, <i>Bacillus coagulans</i> GBI-30 6086 (contains milk)

**Labeling of Maltodextrin, Organic Inulin, Microcrystalline Cellulose and Skim Milk Powder in the ingredient listing is optional.**

## Unacceptable Ingredient Labeling

- **BC30** (Ganeden**BC30**)
- *Bacillus coagulans*
- Ganeden**BC**<sup>30</sup>

## Allergen Listing

Concentration	Description	Ingredient Listing
15 Billion CFU	Kosher Pareve	Contains soy (trace amounts)
15 Billion CFU	Kosher Pareve Allergen Free	None
9 Billion CFU	Kosher Pareve	Contains soy
9 Billion CFU	Kosher Pareve Allergen Free	None
2 Billion CFU	Kosher Pareve	Contains soy (trace amounts)
15 Billion CFU	Kosher Dairy	Contains milk

## Trademark Language

GanedenBC<sup>30</sup> and the GanedenBC<sup>30</sup> logo are registered trademarks of Ganeden, Inc.

## Patent Language

Patents: US 7713726, US 8277799, and patents pending

**If using the probiotic straw on your product, you must include the following language:**

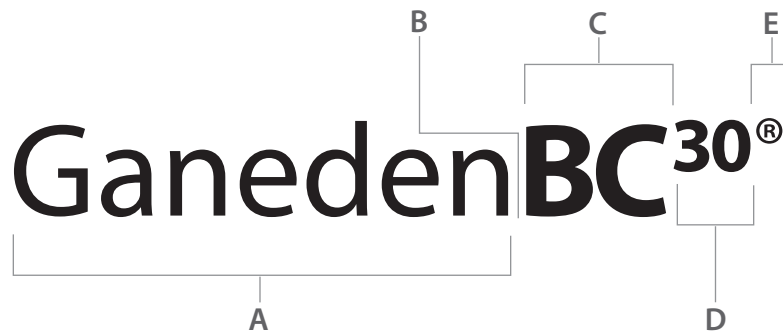
*The <product name> straw is a CapAble AB product and is protected by patent No: EP 1224128*

GanedenBC<sup>30</sup> is not available for use in supplements or OTC products worldwide. **All products containing GanedenBC<sup>30</sup> must be labeled with Nutrition Facts or international equivalents.**

Nutrition Facts	
Serving Size 1/2 cup (115g)	
Servings Per Container About 4	
Amount Per Serving	
Calories 250	Calories from Fat 130
% Daily Value*	
Total Fat 14g	22%
Saturated Fat 9g	45%
Cholesterol 18mg	18%
Sodium 75mg	3%
Total Carbohydrate 26g	9%
Dietary Fiber 0g	0%
Sugars 26g	
Protein 4g	
Vitamin A 10%	Vitamin C 0%
Calcium 10%	Iron 0%
* Percent Daily Values are based on a 2,000 calorie diet.	

Supplement Facts				
Serving Size 1 Packet				
Servings Per Container 10				
Amount Per Serving	AM Packet		PM Packet	
	% Daily Value		% Daily Value	
Vitamin A	2500 IU	50%	2500 IU	50%
Vitamin C	60 mg	100%	60 mg	100%
Vitamin D	400 IU	100%		
Vitamin E	30 mg	100%		
Thiamin	15 mg	100%	15 mg	100%
Riboflavin	17 mg	100%	17 mg	100%
Niacin	20 mg	100%	20 mg	100%
Vitamin B <sub>6</sub>	2.0 mg	100%	2.0 mg	100%
Folic Acid	200 mcg	50%	200 mcg	50%
Vitamin B <sub>12</sub>	3 mcg	50%	3 mcg	50%
Biotin			30 mcg	10%
Pantothenic Acid	5 mg	50%	5 mg	50%

# Correct Printing Format of Ganeden<sup>BC30</sup>



**A** "Ganeden" written in title case (i.e. uppercase "G" followed by lowercase "aneden")

**B** There must be **NO** space between "Ganeden" and "**BC**"

**C** "**BC<sup>30</sup>**" must be bolder than "Ganeden"

**D** "**30**" must be superscript

**E** "®" must be included with first occurrence of "Ganeden<sup>BC<sup>30</sup></sup>" in the document and in all registered trademark statements

**Important**

Ganeden reserves the right to approve usage of the mark Ganeden<sup>BC<sup>30</sup></sup> and the Ganeden<sup>BC<sup>30</sup></sup> logo in all applications.

## 4 Color Process

**Logo\_GanedenBC30\_4C US.ai**

Color may not be changed

## 1 Color

**Logo\_GanedenBC30\_1C US.ai**Color may be changed to  
accommodate project color***Important***Ganeden reserves the right to approve usage of the mark  
GanedenBC<sup>30</sup> and the GanedenBC<sup>30</sup> logo in all applications.

## Additional Information

1. Ganeden does not encourage partners to make cell count claims on food products as storage, shipping and other conditions may affect the cell counts in finished goods. If a partner feels that they must use cell count claims, there are two acceptable methods:
  - a. Perform real time shelf life testing to determine viable cell counts at the end of shelf life
  - b. Utilize an "At Time of Manufacture" statement so long as adequate testing is performed to indicate that at the time of shipment of products to retailers the stated cell count is at or above the stated level. Ganeden recommends utilizing 30% overage on these products.
2. All products must be tested to ensure appropriate viability. This can be performed by the customer using the GanedenBC<sup>30</sup> enumeration protocol as published in the USP FCC or via a validated third party.
3. Ganeden works with our partners to ensure appropriate trademark use. All packaging and marketing materials that utilize the Ganeden or GanedenBC<sup>30</sup> logo or related terms must be preapproved by Ganeden before they are printed or published.
  - a. Send all artwork and marketing materials to  
  
Ganeden  
Attn: Erin Miller, Director of Marketing  
5800 Landerbrook Dr., Suite 300  
Mayfield Hts., OH 44124  
440-229-5214  
emiller@ganedenprobiotics.com
  - b. Artwork and marketing material review and feedback may take up to 2-3 business days.
4. Always consult qualified regulatory counsel relating to claims, packaging and marketing material.
5. Unless there is clinical support for a finished product claim - probiotic claims are to be related to the strain (*Bacillus coagulans* GBI-30, 6086) - **NOT** the finished product.

**Continued on next page »**

6. For both labeling and marketing materials: When you claim/state that Ganeden<sup>BC</sup><sup>30</sup> supports digestive and/or immune health you must add *“as part of a balanced diet and healthy lifestyle.”* This disclaimer must be clear and readable.
7. Disclaimer language should always be on websites. An example would be:

“...is a food product and not a treatment or cure for any medical disorder or disease. If you have any questions relating to immune or digestive health, you should consult a healthcare professional.”
8. If your website contains significant (general) scientific and/or medical information about probiotics, it may also be advisable to add the following language to your disclaimer:

“Not intended as medical advice”