Declaring Voluntary Nutrients on Your Nutrition Facts Label

Presented by ESHA Research

Wednesday, June 8, 2022

11:00 AM PT | 1:00 PM CT | 2:00 PM ET

ESHA Research

ESHA Research was established in 1981 as one of the very first nutrition software solutions. Today, ESHA's suite of nutritional software products, services, and databases are recognized as the industry's top choice for food and supplement formulation, recipe development, labeling, nutritional analysis, and regulatory compliance.

ESHA Solutions

- Genesis R&D® Food Formulation
- Genesis R&D® Supplement Formulation
- REX® Regulations Expert Document Search Portal
- Food Processor® Nutrition & Diet Analysis
- Consulting Services

Our mission is to help remove the complexity of product development and regulatory compliance for the food, beverage, and supplement industries through software, services, and nutritional databases.

Genesis R&D Software

Genesis R&D Foods, first released in 1991, is designed to help users manage processes, overcome industry challenges, and meet federal requirements. Industry professionals use Genesis R&D for quick and accurate nutrient evaluation, virtual product development, nutrition labeling, and regulatory compliance

- Product Development
- Formulation Analysis
- Menu Analysis
- Reporting
- Label Creation
- Regulatory Compliance

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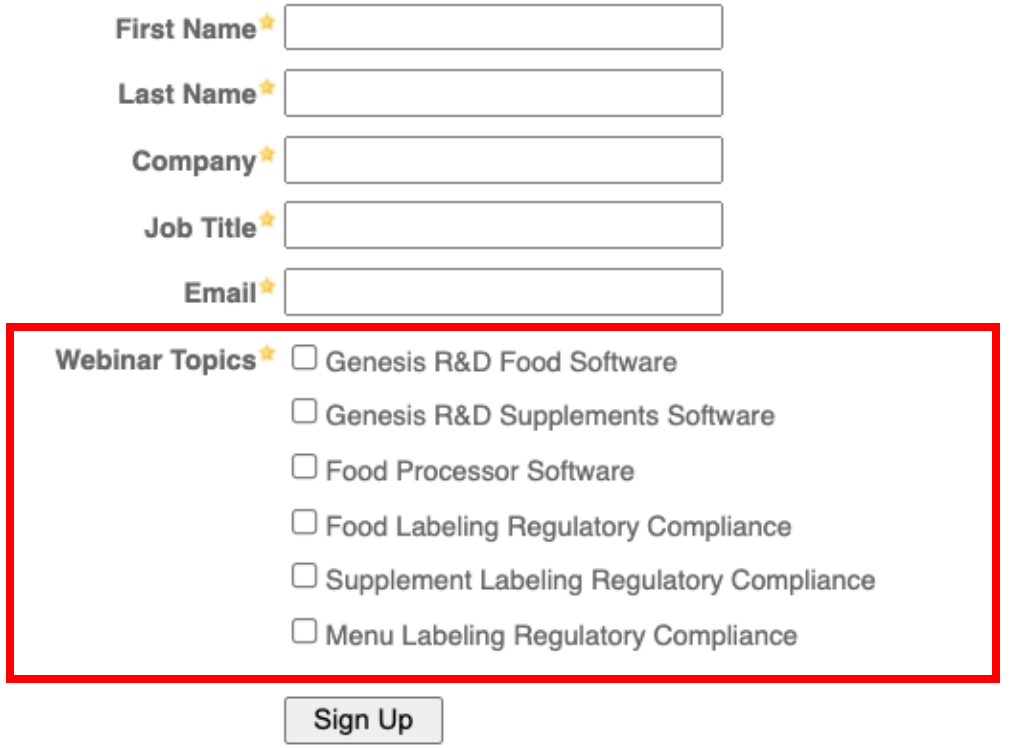

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- ✓The webinar is being recorded
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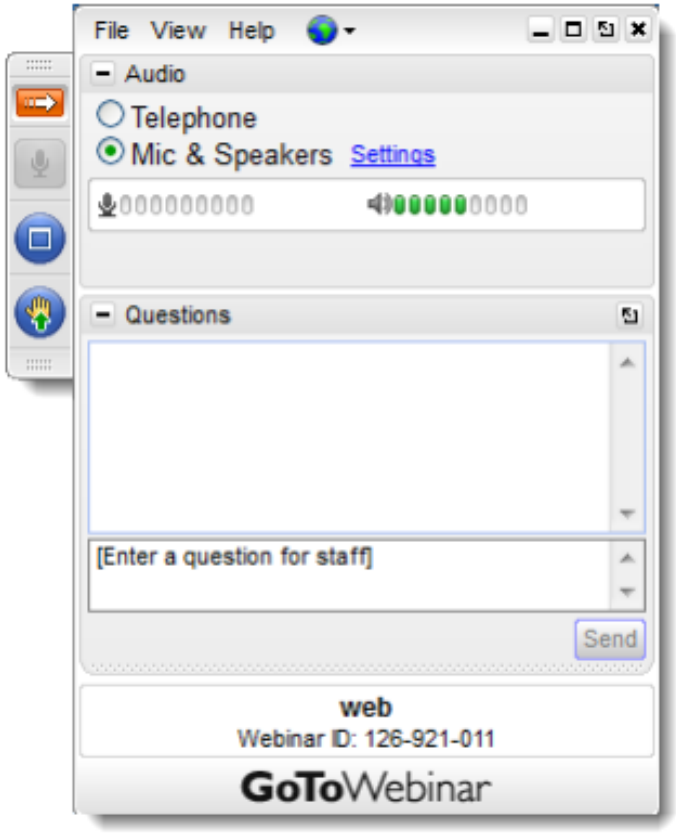


What We'll Cover Today

- Allowed Voluntary Nutrients for U.S. labeling
- When Voluntary Nutrients can or must be declared on the label
- Nutrients that cannot be declared on the label and how to list them on packaging
- How to include Voluntary Nutrients on your label using Genesis R&D
- Q&A

Mandatory U.S. Label Nutrients

- 2016 FDA final rule lists the nutrients that must be reported on the majority of food product labels
- Quantitative amount per serving is declared in most cases; %DV declared for those that apply

Nutrition Facts

8 servings per container

Serving size **1 slice (59g)**

Amount per serving

Calories **180**

	% Daily Value*
Total Fat 6g	**8%**
Saturated Fat 4g	**20%**
Trans Fat 0g	
Cholesterol 25mg	**8%**
Sodium 190mg	**8%**
Total Carbohydrate 30g	**11%**
Dietary Fiber 1g	**4%**
Total Sugars 15g	
Includes 14g Added Sugars	**28%**
Protein 3g	
Vitamin D 0mcg	0%
Calcium 55mg	4%
Iron 2mg	10%
Potassium 1750mg	35%

*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet.

Voluntary U.S. Label Nutrients

- Calories from saturated fat
- Polyunsaturated fat
- Monounsaturated fat
- Fluoride
- Soluble fiber
- Insoluble fiber
- Sugar alcohol
  - Individual sugar alcohol may be listed within the label if the food only contains one type
- Vitamin A
  - Beta Carotene % from
- Vitamin C
- Vitamin E
  - IU
- Vitamin K
- Thiamin
- Riboflavin
- Niacin
- Vitamin B6
- Folate
  - Folic Acid
- Vitamin B12
- Biotin
- Pantothenic acid
- Phosphorus
- Iodine
- Magnesium
- Zinc
- Selenium
- Copper
- Manganese
- Chromium
- Molybdenum
- Chloride
- Choline
- Vitamin D IU

DRVs and RDIs Reference Amounts

- Not all label nutrients have a Daily Value, so %DV is not reported for all
- For those that have %DV listed, DRVs (Daily Reference Values) and RDIs (Reference Daily Intakes) are listed in the CFR

Daily Reference Values (DRVs)		
Food component	Unit of measure	Adults & children (4+ years)
Fat	Grams (g)	78
Saturated fat	Grams (g)	20
Cholesterol	Milligrams (mg)	300
Total carbohydrate	Grams (g)	275
Sodium	Milligrams (mg)	2300
Dietary Fiber	Grams (g)	28
Protein	Grams (g)	50
Added Sugars	Grams (g)	50

Reference Daily Intakes (RDIs)		
Nutrient	Unit of measure	Adults & children (4+ years)
Vitamin D	Micrograms (mcg)	20
Calcium	Milligrams (mg)	1,300
Iron	Milligrams (mg)	18
Potassium	Milligrams (mg)	4,700
Vitamin A	Micrograms RAE (mcg)	900
Vitamin C	Milligrams (mg)	90
Vitamin E	Milligrams (mg)	15
Vitamin K	Micrograms (mcg)	120
Thiamin	Milligrams (mg)	1.2
Riboflavin	Milligrams (mg)	1.3
Niacin	Milligrams NE (mg)	16
Vitamin B6	Milligrams (mg)	1.7
Folate	Micrograms DFE (mcg)	400
Vitamin B12	Micrograms (mcg)	2.4
Biotin	Micrograms (mcg)	30
Pantothenic acid	Milligrams (mg)	5
Phosphorus	Milligrams (mg)	1,250
Iodine	Micrograms (mcg)	150
Magnesium	Milligrams (mg)	420
Zinc	Milligrams (mg)	11
Selenium	Micrograms (mcg)	55
Copper	Milligrams (mg)	0.9
Manganese	Milligrams (mg)	2.3
Chromium	Micrograms (mcg)	35
Molybdenum	Micrograms (mcg)	45
Chloride	Milligrams (mg)	2,300
Choline	Milligrams (mg)	550

Rounding and Declarations

Fats and Fatty Acids, Carbohydrates – Fiber, Sugar, Sugar Alcohols, Protein, etc.

- Rounding rules listed in each nutrient section of 101.9

Vitamins and Minerals

- Final Rule
  - Using levels of significance given in the CFR; additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts
- FDA Guidance – December 2019
  - Includes options and instruction for levels of significance and rounding

Contains Nonbinding Recommendations

Recommendations for declaration of quantitative amounts of vitamins and minerals on the Nutrition and Supplement Facts labels using RDIs for adults and children ≥ 4 years

Nutrient	Unit of Measure	RDI for Adults and Children ≥ 4 years	Recommended increment
Vitamin A	Micrograms RAE (mcg)	900	Nearest 10 mcg
Vitamin C	Milligrams (mg)	90	Nearest mg
Calcium	Milligrams (mg)	1,300	Nearest 10 mg
Iron	Milligrams (mg)	18	Nearest .1 mg
Vitamin D	Micrograms (mcg)	20	Nearest .1 mcg
Vitamin E	Milligrams (mg)	15	Nearest .1 mg
Vitamin K	Micrograms (mcg)	120	Nearest mcg
Thiamin	Milligrams (mg)	1.2	Nearest .01 mg
Riboflavin	Milligrams (mg)	1.3	Nearest .01 mg
Niacin	Milligrams NE (mg)	16	Nearest .1 mg
Vitamin B_6	Milligrams (mg)	1.7	Nearest .01 mg
Folate	Micrograms DFE (mcg)	400	Nearest 5 mcg
Vitamin B_{12}	Micrograms (mcg)	2.4	Nearest .01 mcg
Biotin	Micrograms (mcg)	30	Nearest .1 mcg
Pantothenic acid	Milligrams (mg)	5	Nearest .1 mg
Phosphorus	Milligrams (mg)	1,250	Nearest 10 mg
Iodine	Micrograms (mcg)	150	Nearest mcg
Magnesium	Milligrams (mg)	420	Nearest 5 mg
Zinc	Milligrams (mg)	11	Nearest .1 mg
Selenium	Micrograms (mcg)	55	Nearest mcg
Copper	Milligrams (mg)	0.9	Nearest .01 mg
Manganese	Milligrams (mg)	2.3	Nearest .01 mg
Chromium	Micrograms (mcg)	35	Nearest .1 mcg
Molybdenum	Micrograms (mcg)	45	Nearest .1 mcg
Chloride	Milligrams (mg)	2,300	Nearest 10 mg
Potassium	Milligrams (mg)	4,700	Nearest 10 mg
Choline	Milligrams (mg)	550	Nearest 10 mg

This table provides recommendations for the declaration of quantitative amounts of vitamins and minerals using only the RDIs that have been established for adults and children 4 years of age and older. Our regulations, at 21 CFR 101.9(c)(8)(iv), provide RDIs for infants through 12 months, children 1 through 3 years, and pregnant and lactating women. The declaration recommendations provided in this guidance can also be applied to the RDIs for these subpopulations.

When Must They Be Declared?

- Polyunsaturated or Monounsaturated
  - If either is declared, the other must also be declared
- Folic Acid
  - If added directly to the food, Folate and Folic Acid must be declared
- Claims
  - If claims are made about a nutrient, then that nutrient and in some cases, related nutrients must be declared

"Cholesterol Free" Mono and Polyunsaturated Fats might be required

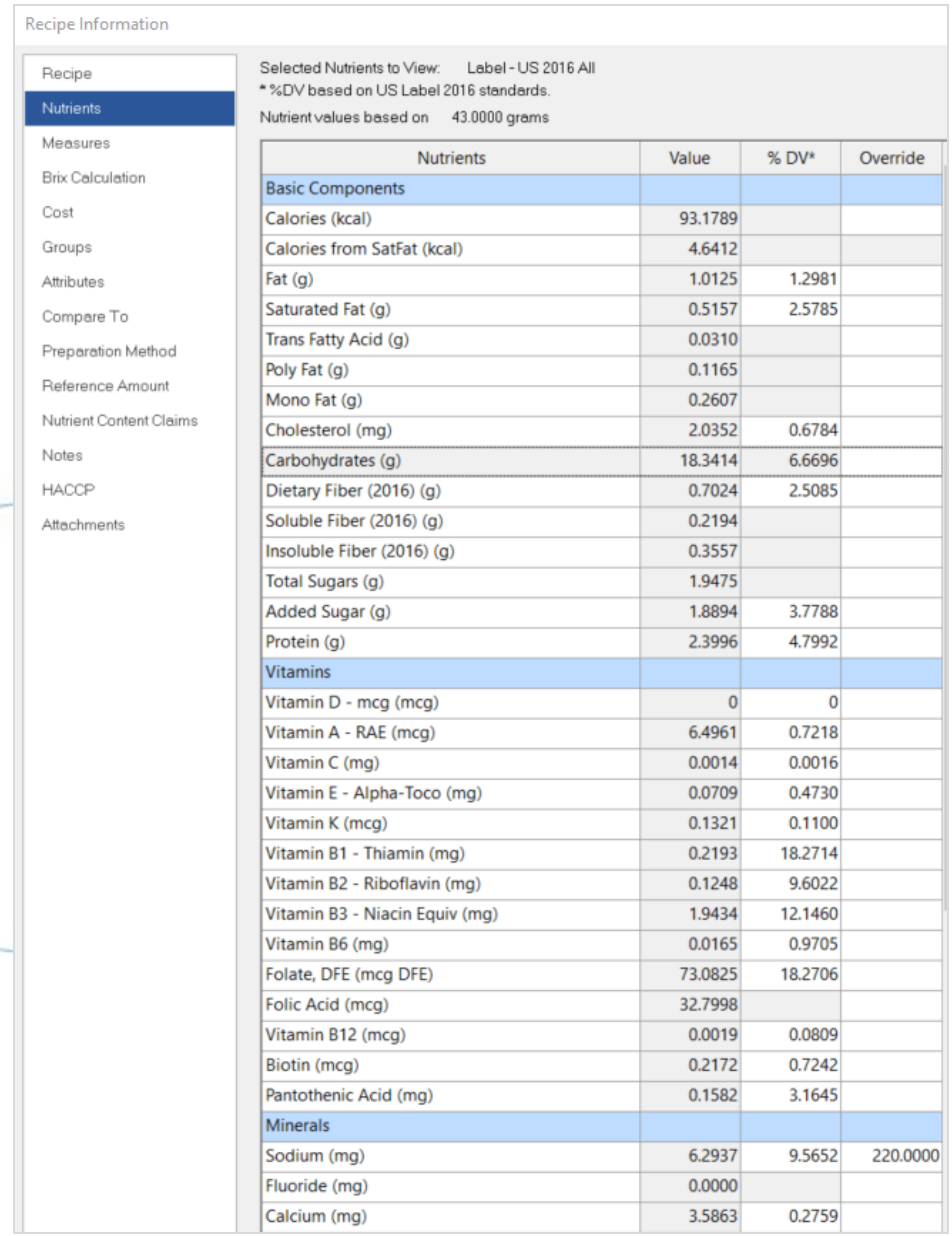
"Sugar Free" Sugar Alcohol might be required

"High in Antioxidants…" list the specific vitamin(s)

Know the Claims *conditions* and *requirements* and report the necessary nutrients to support the claims

Declaration of Components Outside of the Nutrition Facts

- Nutrients and components that do not have an RDI/DRV and are not allowed within the Nutrition Facts label can be declared on packaging
  - Outside of the Nutrition Facts label
  - Factual statement regarding the amount or percent of content per serving is allowed
  - Must be truthful and not misleading
  - May not characterize the level of nutrient or component, such as with a “High in” or “Excellent source of” type claim

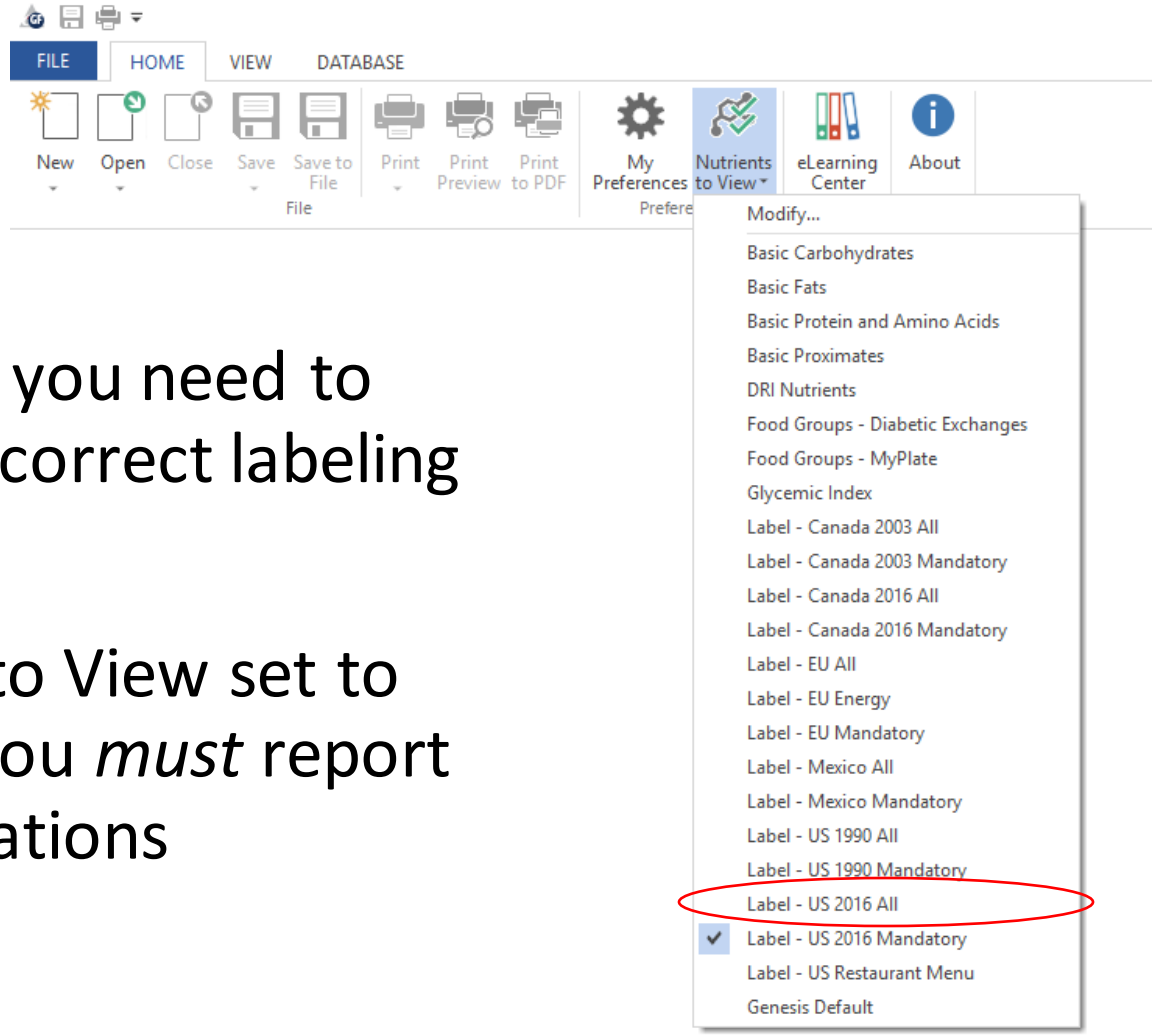


Nutrients	Value	% DV*	Override
Basic Components			
Calories (kcal)	93.1789		
Calories from SatFat (kcal)	4.6412		
Fat (g)	1.0125	1.2981	
Saturated Fat (g)	0.5157	2.5785	
Trans Fatty Acid (g)	0.0310		
Poly Fat (g)	0.1165		
Mono Fat (g)	0.2607		
Cholesterol (mg)	2.0352	0.6784	
Carbohydrates (g)	18.3414	6.6696	
Dietary Fiber (2016) (g)	0.7024	2.5085	
Soluble Fiber (2016) (g)	0.2194		
Insoluble Fiber (2016) (g)	0.3557		
Total Sugars (g)	1.9475		
Added Sugar (g)	1.8894	3.7788	
Protein (g)	2.3996	4.7992	
Vitamins			
Vitamin D - mcg (mcg)	0	0	
Vitamin A - RAE (mcg)	6.4961	0.7218	
Vitamin C (mg)	0.0014	0.0016	
Vitamin E - Alpha-Toco (mg)	0.0709	0.4730	
Vitamin K (mcg)	0.1321	0.1100	
Vitamin B1 - Thiamin (mg)	0.2193	18.2714	
Vitamin B2 - Riboflavin (mg)	0.1248	9.6022	
Vitamin B3 - Niacin Equiv (mg)	1.9434	12.1460	
Vitamin B6 (mg)	0.0165	0.9705	
Folate, DFE (mcg DFE)	73.0825	18.2706	
Folic Acid (mcg)	32.7998		
Vitamin B12 (mcg)	0.0019	0.0809	
Biotin (mcg)	0.2172	0.7242	
Pantothenic Acid (mg)	0.1582	3.1645	
Minerals			
Sodium (mg)	6.2937	9.5652	220.0000
Fluoride (mg)	0.0000		
Calcium (mg)	3.5863	0.2759	

Genesis R&D – Populate All Declared Fields

- Best practice is to populate all nutrient fields for which you have information
- However, if you choose to declare voluntary nutrients, you *must* ensure that ingredients have been reviewed and report information for those voluntary nutrients appropriately
- Contact suppliers for additional nutrient detail when needed
- Populate nutrient information using the correct unit and corresponding field

Nutrients to View



- Consider the nutrients that you need to populate for complete and correct labeling
- Label – US 2016 All
- Create a custom Nutrients to View set to include the nutrients that you *must* report for specific foods or formulations

Review the Spreadsheet Report

Complete and correct entry of Ingredients contributes to accurate and compliant recipe analysis and labels. Review the Spreadsheet report for ALL *Recipes* to ensure that required information is reported. Identify missing values (indicated by dashes) and populate the **Ingredient record** to fill in the blanks.

Spreadsheet: Bread *

Item Name	Quantity	Measure	Cals (kcal)	SatCals (kcal)	Fat (g)	SatFat (g)	TransFat (g)	PolyFat (g)	MonoFat (g)	Chol (mg)	Carb (g)	Fib(16) (g)	SolFib(... (g)	InsolFib(1... (g)	Sugar (g)	SugAdd (g)	Prot (g)	Vit D-mcg (mcg)	Vit A-RAE (mcg)	Vit C (mg)	Vit E-a-To (mg)
Bread	1	Serving	93.1789	4.6412	1.0125	0.5157	0.0310	0.1165	0.2607	0.5000	18.3414	0.7024	0.2194	0.3557	1.9475	1.8894	2.3996	0	6.4961	0.0014	0.07
flour, all purpose, white, unbleached, enriched	0.046955	Pound	77.5268	0.2971	0.2087	0.0330	0	0.0880	0.0185	0	16.2529	0.5751	0.2194	0.3557	0.0575	0	2.2001	0	0.0213	0	0.04
water, distilled	0.052141	Pound	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
sugar, white, granulated	0.004174	Pound	7.3267	0	0	0	0	0	0	0	1.8928	0	0	0	1.8894	1.8894	0	0	0	0	
yeast, bakers, active, dry	0.001043	Pound	1.5382	0.0426	0.0360	0.0047	0	0.0001	0.0204	0	0.1951	0.1273	--	--	0	0	0.1914	0	0	0.0014	
salt, table	0.000031	Pound	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
butter, unsalted for butter top bread	0.002087	Pound	6.7871	4.3015	0.7678	0.4779	0.0310	0.0285	0.2218	2.0352	0.0006	0	0	0	0.0006	0	0.0080	0	6.4748	0	0.02
Moisture Adjustment: Loss	20.0000	Percent																			
Total	1	Serving	93.1789	4.6412	1.0125	0.5157	0.0310	0.1165	0.2607	0.5000	18.3414	0.7024	0.2194	0.3557	1.9475	1.8894	2.3996	0	6.4961	0.0014	0.07
% Recommendation (US Label Adult (2016))					1.2981	2.5785				0.1667	6.6696	2.5085				3.7788	4.7992	0	0.7218	0.0016	0.47

Genesis R&D Uses Regulatory Label Units and Rounding

- Uses proper label units
- Applies proper rounding
- Label features provide allowed options for declaration

Nutrition Facts

Serving size	**1 each (50g)**
Amount per serving	
Calories	**170**
Calories from Saturated Fat	50
	% Daily Value*
Total Fat 10g	**13%**
Saturated Fat 6g	**30%**
Trans Fat 0g	
Polyunsaturated Fat 0.5g	
Monounsaturated Fat 3g	
Cholesterol 45mg	**15%**
Sodium 15mg	**1%**
Fluoride 0mg	
Total Carbohydrate 18g	**7%**
Dietary Fiber 2g	**7%**
Soluble Fiber 1g	
Insoluble Fiber 1g	
Total Sugars 1g	
Includes 0g Added Sugars	**0%**
Sugar Alcohol 0g	
Protein 3g	

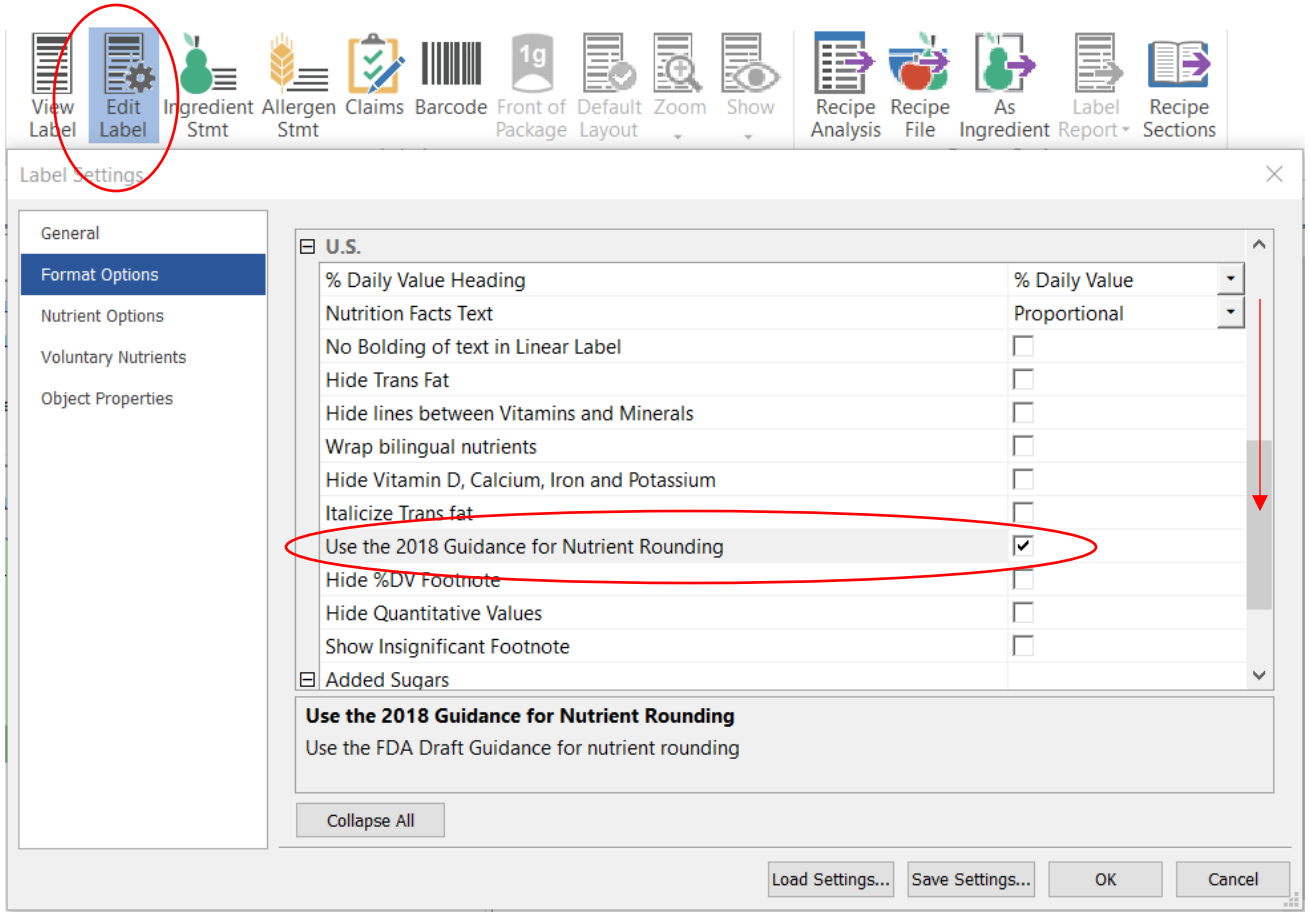
Vitamin D 1mcg 6%	•	Calcium 260mg 20%
Iron 1mg 6%	•	Potassium 564mg 10%
Vitamin A 90mcg 10%	•	Vitamin C 20mg 20%
Vitamin E 1mg 6%	•	Vitamin K 2mcg 2%
Thiamin 0.2mg 15%	•	Riboflavin 0.2mg 15%
Niacin 2mg 15%	•	Vitamin B_6 0.1mg 6%
Folate 68mcg DFE 15%	•	Vitamin B_{12} 0.1mcg 4%
Biotin 1mcg 4%	•	Pantothenic Acid 2mg 40%
Phosphorus 46mg 4%	•	Iodine 6mcg 4%
Magnesium 8mg 2%	•	Zinc 1mg 10%
Selenium 10mcg 20%	•	Copper 0.1mg 10%
Manganese 0.2mg 8%	•	Chromium 1mcg 2%
Molybdenum 1mcg 2%	•	Chloride 46mg 2%
Choline 23mg 4%		

*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Vitamins and Minerals Rounding

To select the FDA Guidance rounding for vitamins and minerals option:

- Edit Label
- Format Options
- U.S. section



Best Practices for Documentation

- Supplier sheets for ingredients that you add to your software
- Lab results and notes regarding any determinations or adjustments that you've applied to your Recipes
- Use the User-Code field in Genesis R&D to help track Ingredients and Recipes
- Use the Attachments function to link supporting documentation directly to Ingredient and Recipe records in Genesis R&D

Genesis R&D Training

Location Options:

- ESHA Training Center (Oak Brook, IL)
- Online

Session Options:

- Professional (12 CPE Credits)
- Advanced* (6 CPE Credits)
- Combined Professional and Advanced

*(***Prerequisite***: Professional Training)*

Location	Dates	Course
Online	June 13-16, 2022 June 21-22, 2022	4-Day Genesis R&D Foods Professional 2-Day Genesis R&D Foods Advanced
ESHA Training Center Oak Brook, IL	July 19-20, 2022 July 21, 2022	2-Day Genesis R&D Foods Professional 1-Day Genesis R&D Foods Advanced
Online	Aug. 15-18, 2022 Aug. 23-24, 2022	4-Day Genesis R&D Foods Professional 2-Day Genesis R&D Foods Advanced

Course Overview

Genesis R&D Foods Professional - This training session covers the fundamentals of the Genesis R&D Food program with a primary focus on FDA regulations: creating ingredients and composite ingredients, building recipes/formulas, nutrition analysis, moisture loss, reporting, labeling, best practices, and much more. In addition, this session covers a comprehensive regulatory review.

Genesis R&D Foods Advanced Training - The Advanced session builds upon the skills learned in the Professional training and offers deeper learning on topics including PDCAAS, International Food Labeling, Advanced Label Settings, and more.

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