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
• 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 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
- Regulatory Compliance
Upcoming Webinars

April 15, 2020 | Genesis R&D Foods Nutrition Reports Overview
The Genesis R&D Foods program offers a variety of reports to help you analyze your formulas and recipes. During this webinar, we review the different nutrition analysis reports, report options, customizations, printing, and exporting.

To register or view archived webinars please visit: www.esha.com/news-events/webinars

Stay tuned for more
Please Note!

- The webinar is being recorded
- All webinars available on our website
- Submit your questions in the GoToWebinar control panel
- We’ll email a copy of the recording and the slides following the webinar
What we’ll cover today

• Label Format Highlights
• Serving Sizes
• Voluntary Nutrients
• Rounding Options
• View Label Screen
**Nutrition Facts**

<table>
<thead>
<tr>
<th>Servings per container</th>
<th>12 servings per container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serving size</td>
<td>2 slices (50g)</td>
</tr>
<tr>
<td>Amount per serving</td>
<td></td>
</tr>
<tr>
<td>Calories</td>
<td>220</td>
</tr>
<tr>
<td></td>
<td>% Daily Value*</td>
</tr>
<tr>
<td>Total Fat 6g</td>
<td>8%</td>
</tr>
<tr>
<td>Saturated Fat 3.5g</td>
<td>18%</td>
</tr>
<tr>
<td>Trans Fat 0g</td>
<td>0%</td>
</tr>
<tr>
<td>Cholesterol 60mg</td>
<td>20%</td>
</tr>
<tr>
<td>Sodium 300mg</td>
<td>13%</td>
</tr>
<tr>
<td>Total Carbohydrate 36g</td>
<td>13%</td>
</tr>
<tr>
<td>Dietary Fiber 0g</td>
<td>0%</td>
</tr>
<tr>
<td>Total Sugars 4g</td>
<td>6%</td>
</tr>
<tr>
<td>Includes 3g Added Sugars</td>
<td></td>
</tr>
<tr>
<td>Protein 5g</td>
<td>0%</td>
</tr>
<tr>
<td>Vitamin D 0mcg</td>
<td>0%</td>
</tr>
<tr>
<td>Calcium 34mg</td>
<td>2%</td>
</tr>
<tr>
<td>Iron 1mg</td>
<td>6%</td>
</tr>
<tr>
<td>Potassium 68mg</td>
<td>2%</td>
</tr>
</tbody>
</table>

*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.

**Nutrition Facts**

<table>
<thead>
<tr>
<th>Servings per container</th>
<th>40 servings per container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serving size</td>
<td>1 tsp (0.6g)</td>
</tr>
<tr>
<td>Amount per serving</td>
<td></td>
</tr>
<tr>
<td>Calories</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>% Daily Value*</td>
</tr>
<tr>
<td>Total Fat 0g</td>
<td>0%</td>
</tr>
<tr>
<td>Sodium 0mg</td>
<td>0%</td>
</tr>
<tr>
<td>Total Carbohydrate 1g</td>
<td>0%</td>
</tr>
<tr>
<td>Protein 0g</td>
<td></td>
</tr>
</tbody>
</table>

Not a significant source of saturated fat, trans fat, cholesterol, dietary fiber, total sugars, added sugars, vitamin D, calcium, iron and potassium.

*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.

**Nutrition Facts**

Servings per container 40, Serving size 1 tsp (0.6g), Amount per serving:

**Calories 0**, Total Fat 0g (0% DV), Sodium 0mg (0% DV), Total Carbohydrate 1g (0% DV), Protein 0g. The % Daily Value (DV) 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.

*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.

and many more
Actual Non-Compliant Label Example

- Improper label format style and spacing
- Incorrect Nutrients, units, and %DV

What could happen when you don’t apply the proper CFR layout and design specifications
Let Genesis R&D Do the Work for You

Genesis R&D provides:

• Templates with correct style and spacing that follow the CFR guidelines

• Proper nutrients, units, and %DV

• Compliant adjustments according to the regulations you work in (e.g. from U.S. 1990 to 2016 components)

What happens with a Genesis R&D formatted label
Voluntary Nutrients for U.S. Labels

- Biotin
- Calories from Saturated Fat
- Chloride
- Choline
- Chromium
- Copper
- Fluoride
- Folate
- Insoluble Fiber
- Iodine
- Magnesium
- Manganese
- Molybdenum
- Monounsaturated Fat
- Pantothenic Acid
- Phosphorus
- Polyunsaturated Fat
- Selenium
- Soluble Fiber
- Sugar Alcohol
- Vitamin A
- Vitamin B1
- Vitamin B12
- Vitamin B2
- Vitamin B3
- Vitamin B6
- Vitamin C
- Vitamin E
- Vitamin K
- Zinc
Declaration of Quantitative Amounts of Vitamins and Minerals

DV for label nutrients vary greatly
e.g. from 0.9 mg for Copper to 4700 mg for Potassium

It is appropriate to apply different rounding precision to
nutrients that have smaller or larger quantitative values

Levels of significance: refer to the degree of accuracy
when rounding nutrients for purposes of declaring
quantitative amounts of vitamins and minerals on the
label.
FDA Guidance for Vitamins and Minerals

When the DV Value is:

**Less than 5 mg or mcg**, appropriate to declare the quantitative amounts to the nearest hundredth of a mg or mcg:
- Thiamin, Riboflavin, Riboflavin, Vitamin B6, Vitamin B12, Copper, and Manganese

**At least 5 mg or mcg, but less than 50 mg or mcg**; can report to the nearest tenth of mg or mcg:
- Iron, Vitamin D, Vitamin E, Niacin, Biotin, Pantothenic Acid, Zinc, Chromium, and Molybdenum

**At least 50 mg or mcg, but less than 250 mg or mcg**; can report to the nearest mg or mcg:
- Vitamin C, Vitamin K, Iodine, and Selenium

**At least 250 mg or mcg, but less than 500 mg or mcg**; can report to the nearest 5 mg or mcg:
- Folate and Magnesium

**500 mg or mcg or greater**; can report to the nearest 10 mg or mcg:
- Vitamin A, Calcium, Phosphorus, Chloride, Potassium, and Choline
## FDA Guidance Rounding

### December 2019: Q&A on the Declaration of Quantitative Amounts of Vitamins and Minerals

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Amount</th>
<th>% Daily Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein 4g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin D 0mcg</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Calcium 28mg</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>Iron 1mg</td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td>Potassium 64mg</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>Thiamin 0.3mg</td>
<td>25%</td>
<td></td>
</tr>
<tr>
<td>Riboflavin 0.2mg</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td>Niacin 3mg</td>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>Folate 100mcg DFE (45mcg folic acid)</td>
<td>25%</td>
<td></td>
</tr>
</tbody>
</table>

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**Original**

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<tbody>
<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin D 0.2mcg</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>Calcium 30mg</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>Iron 1.4mg</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td>Potassium 60mg</td>
<td>2%</td>
<td></td>
</tr>
<tr>
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<td>25%</td>
<td></td>
</tr>
<tr>
<td>Riboflavin 0.21mg</td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td>Niacin 2.8mg</td>
<td>20%</td>
<td></td>
</tr>
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**FDA Guidance Rounding applied**
In Genesis R&D, View Label shows you:

- **Label** – with format based on your Edit Label settings
- **Ingredient List**
- **Allergen Lists**
- **and more**
Genesis R&D Training

Genesis R&D Training | April 28-30, 2020 | Web-based
Professional and/or Advanced training session. The first two days cover the fundamentals of the Genesis R&D Food program: creating ingredients, building recipes/formulas, nutrition analysis and reporting, labeling, and best practices. In addition, you can attend a third day of Advanced instruction, or just attend the Advanced session as a single day. Advanced training presents more complex scenarios and more comprehensive regulatory issues.

Instruction covers the fundamentals of the Genesis R&D Food program: creating ingredients, building recipes/formulas, nutrition analysis and reporting, labeling, and best practices. In addition, the class includes direction and discussion on the 2018 Menu Labeling requirements and Menu Label features in Genesis R&D.

Genesis R&D Training: Canadian Labeling | June 16-17, 2020 | Oak Brook, IL
Professional training session with Canadian labeling. This two-day class cover the fundamentals of the Genesis R&D Food program: creating ingredients, building recipes/formulas, nutrition analysis and reporting, labeling, and best practices. In addition, the labeling instruction focuses on Canadian labeling regulation and creation.

Contact training@esha.com with any questions.
See the Full 2020 Schedule: https://www.esha.com/news-events/training-schedule/
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