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Presented by ESHA Research

Wednesday, January 12, 2022
11:00 AM PT | 1:00 PM CT | 2:00 PM ET
ESHA Research

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What We’ll Cover Today

• REX Overview
• Searching
• Review Search Results
• Viewing Documents
• Bookmarking Favorites
• Q&A
Introducing: REX®

REX is ESHA Research’s online documentation portal that provides quick and easy access to regulatory and guidance documentation relevant to the food and supplement manufacturing industries.

Resources
• FDA final rule and guidance documents
• USDA final rule and guidance documents
• Relevant documents for labeling
• Curated by ESHA
Searching

- Enter full or partial words to the search bar
- Narrow your search by source, date, type, and category
- Sort results by Relevance (default) or by date in ascending (ACS) or descending (DESC) order.
Matching Search Results

View number of match hits from each source:

- **CFR** - 1 document - 4 instances
- **FDA** - 31 documents - 132 instances
- **Other** - 2 documents - 15 instances
- **USDA** - 19 documents - 75 instances
Preview Result Details

The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels

6/1/2018

Page 1

Contains Nonbinding Recommendations. The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels. Guidance for industry. Additional copies are available from: Office of... 

Page 3

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The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels: Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance is intended to identify for manufacturers specific, additional isolated or synthetic non-digestible carbohydrates that we intend to propose adding to the list of those that meet our regulatory definition of “dietary fiber” (21 CFR 101.9(e)(6))). This guidance also is intended to advise manufacturers of our intent to exercise enforcement discretion relative to the declaration of these isolated or synthetic non-digestible carbohydrates as a dietary fiber on Nutrition Facts and Supplement Facts labels, and for the use of a caloric value for polydextrose of 1 kcal/g, pending completion of a rulemaking regarding revising our regulations. The following isolated or synthetic non-digestible carbohydrates are subject to our intent to exercise enforcement discretion: mixed plant cell wall fibers; arabinoxylan; alginic acid; inulin and inulin-type fructans; high amylose starch (resistant starch 2); galactooligosaccharides; polydextrose; and resistant maltoolxtrextrins/dextrins.

This guidance is effective immediately because we have determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)).
Bookmarking Favorites

BOOKMARK IMPORTANT DOCUMENTS

Questions and Answers

Resources

- Science Review of Isolated and Synthetic Non-Digestible Carbohydrates (/food/labeling-nutrition/science-review-isolated-and-synthetic-non-digestible-carbohydrates)
- Labeling Guidance Documents (/labeling-nutrition)

General Questions

- What actions has FDA taken on dietary fiber?
Reference Bookmarked Documents

ALL BOOKMARKED DOCUMENTS ARE SAVED HERE FOR QUICK AND EASY FUTURE ACCESS
Genesis R&D Software

Genesis R&D Foods and Genesis R&D Supplements programs are designed to help users manage formulation and labeling processes and comply with federal requirements.

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

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Nutrition Facts
8 servings per container
Serving size 1 slice (59g)

Amount per serving
Calories 180

% Daily Value*

Total Fat 8g 8%
Saturated Fat 4g 20%
Trans Fat 0g
Cholesterol 25mg 8%
Sodium 190mg 8%
Total Carbohydrate 28g 10%
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 268mg 6%

*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.
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REX + Genesis R&D Record-Keeping

• Genesis R&D users can attach documents to Recipes, Ingredients, Labels, and Food Menus.
• Various file types can be attached to a record including PDF, JPG, CSV, MP4, and more.
GET STARTED TODAY!

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