

dental caries because they are slowly metabolized by bacteria to form some acid. The rate and amount of acid production is significantly less than that from sucrose and does not cause the loss of important minerals from tooth enamel.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met, except that sugar alcohol-containing foods are exempt from section § 101.14(e)(6).

(2) *Specific requirements.* (i) *Nature of the claim.* A health claim relating sugar alcohols and the nonpromotion of dental caries may be made on the label or labeling of a food described in (c)(2)(ii) of this section, provided that:

(A) The claim shall state "does not promote," "useful in not promoting," or "expressly for not promoting" dental caries.

(B) In specifying the disease, the claim uses the following terms: "dental caries" or "tooth decay."

(C) For packages with a total surface area available for labeling of 15 or more square inches, the claim shall indicate that dental caries depends on many factors.

(D) Packages with a total surface area available for labeling of less than 15 square inches are exempt from paragraph (C) of this section.

(E) The claim shall not attribute any degree of nonpromotion of dental caries to the use of the sugar alcohol-containing food.

(ii) *Nature of the food.* (A) The food shall meet the requirement in § 101.60(c)(1)(i) with respect to sugars content.

(B) The sugar alcohol in the food shall be xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, or a combination of these.

(C) The sugar alcohol-containing food shall not lower plaque pH below 5.7 by bacterial fermentation either during consumption or up to 30 minutes after consumption, as measured by in vivo tests.

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section, which describe the relationship between diets containing sugar alcohols and dental caries.

(2) In referring to sucrose, the claim may use the term "sucrose" or "sugar."

(3) The claim may identify one or more of the following risk factors for dental caries: Frequent consumption of sucrose or other fermentable carbohydrates; presence of oral bacteria capable of fermenting sugars; length of time sugars are in contact with the teeth;

lack of exposure to fluoride; individual susceptibility; socioeconomic and cultural factors; and characteristics of tooth enamel, saliva, and plaque.

(e) *Model health claim.* The following model health claims may be used in food labeling to describe the relationship between sugar alcohol and dental caries.

(1) For packages with total surface area available for labeling of less than 15 square inches:

(i) Useful only in not promoting tooth decay;

(ii) Does not promote tooth decay; and

(iii) [This product] does not promote tooth decay.

(2) For packages with total surface area available for labeling of 15 or more square inches:

(i) Tooth decay is a disease caused by many factors including frequent between meal consumption of sugary foods. [Name of sugar alcohol] does not promote tooth decay.

(ii) [Reserved].

Dated: July 7, 1995.

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**Note:** The following tables will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-P