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*NOT ADMITTED IN DC

April 30, 2001

RECEIVED
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OFFICE OF
PREMARKET APPROVAL

BY HAND DELIVERY

Office of Premarket Approval (HFS-200)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C St. SW
Washington, DC 20204

Subject: Notice of a GRAS Exemption for Erythritol

Dear Sir/Madam:

Pursuant to the proposed rule outlined at 62 Fed. Reg. 18939 (April 17, 1997), Cerestar Holding, B.V. hereby submits notification that use of erythritol as a flavor enhancer, formulation aid, humectant, nutritive sweetener, stabilizer and thickener, sequestrant, and texturizer in foods is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because the notifier has determined that such use is generally recognized as safe (GRAS). To facilitate your review, this notification is submitted in the format suggested under proposed 21 C.F.R. § 170.36(c) (see 62 Fed. Reg. at 18961). Also enclosed is an electronic copy (Microsoft Word 97) of the GRAS Exemption Claim (GRAS Exemption Claim.doc) and Additional Information (GRAS Additional Information.doc) documents.

Sincerely,

Diane B. McColl
Counsel to Cerestar Holding, B.V.

000002

2603 MAIN STREET
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IRVINE, CALIFORNIA 92614
(949) 553-7400
FAX. (949) 553-7433

4819 EMPEROR BOULEVARD
SUITE 400
DURHAM, NORTH CAROLINA 27703
(919) 313-4750
FAX (919) 313-4751

GRAS EXEMPTION CLAIM

We hereby claim that the use of erythritol as a flavor enhancer, formulation aid, humectant, nutritive sweetener, stabilizer and thickener, sequestrant, and texturizer in foods is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because we have determined that such use of erythritol is generally recognized as safe (GRAS).

(1) Name and address of the notifier:

Peter de Cock
Global Business Development Manager
Cerestar Holding B.V.
Havenstraat 84, B-1800 Vilvoorde
Phone: 011 232 2 257 0654
Fax: 011 32 2 257 0780

(2) Common or usual name of the substance that is the subject of the GRAS exemption claim:

Erythritol

(3) Applicable conditions of use of the notified substance:

(a) Foods in which the substance is to be used:

Bakery fillings, cakes and cookies, chewing gum, dairy drinks, fat-based cream used in modified fat/calorie cookies, cakes and pastries, hard candies, frozen dairy desserts, puddings, reduced and low calorie carbonated and non-carbonated beverages, soft candies, sugar substitutes, and yogurt.

(b) Levels of use in such foods:

	Maximum Use
Bakery fillings (fruit, custard, cream, pudding)	15%
Cakes and cookies (regular and dietetic)	15%
Chewing gum	60%
Dairy drinks (chocolate and flavored milks)	3.5%
Fat-based cream used in modified fat/calorie cookies, cakes and pastries	60%
Hard candies (including pressed candy, mints and cough drops)	99%
Frozen dairy desserts (regular ice cream, soft serve, sorbet)	10%
Puddings (instant, phosphate set)	10%
Reduced- and low-calorie carbonated and non-carbonated beverages	3.5%
Soft Candies (non-chocolate, plain chocolate, chocolate coated)	60%
Sugar substitutes (carrier)	100%
Yogurt (regular and frozen)	10%

(c) Purposes for which the substance is used:

Flavor enhancer, formulation aid, humectant, nutritive sweetener, stabilizer and thickener, sequestrant, texturizer.

(d) Description of the population expected to consume the substance:

Members of the general population who consume at least one of the food categories described above.

(4) Basis for the GRAS determination:

The basis of the GRAS determination is through scientific procedures.

(5) Review and Copying Statement:

The data and information that are the basis for Cerestar Holding B.V.'s GRAS determination are available for the Food and Drug Administration's (FDA's) review and copying at reasonable times at the offices of the notifier, or will be sent to FDA upon request.

Peter de Cock
Global Business Development Manager
Cerestar Holding B.V.

Please address correspondence to:

Diane B. McColl
Counsel to Cerestar Holding B.V.
Hyman, Phelps and McNamara, P.C.
700 Thirteenth Street N.W.
Suite 1200
Washington, D.C. 20005
Phone: 202-737-4291
Fax: 202-737-9329

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ADDITIONAL INFORMATION

(1) Identity of the notified substance

(a) Chemical name

1,2,3,4-butanetetrol

Synonyms: *meso*-erythritol, tetrahydroxybutane, erythrol, erythrite, erythroglucin, antierythrite, and phycite

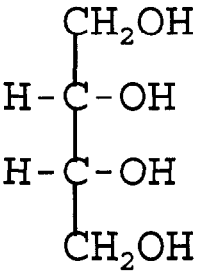
(b) Chemical Abstracts Service (CAS) Registry Number

149-32-6 (*meso*-erythritol)

(c) Empirical formula

$C_4H_{10}O_4$

(d) Structural formula



(e) Method of manufacture

Erythritol is manufactured through pure culture fermentation using a non-toxigenic, non-pathogenic microorganism that acts upon a carbohydrate-based medium. The fermentation broth containing erythritol is separated from the organisms and subjected to purification treatment similar to those for the carbohydrate sweeteners and sugar alcohols, *e.g.*, ion-exchange resin, activated charcoal, ultrafiltration and crystallization. The final product is a material containing not less than 99.5% erythritol.

(i) Fermentation Process

The manufacturing process for erythritol is based on the fermentative conversion of glucose into erythritol catalyzed by a microorganism named *Moniliella pollinis* (previously named *Tomentosa var. pollinis*) followed by separation and purification from the fermented liquor.

For the fermentation process, the strain inoculum preparation is transferred under aseptic conditions into a flask containing sterile medium. The sterile media used for the seed cultures and for the production cultures contain glucose syrup, corn steep liquor, and antifoaming agents. All ingredients used are of food grade quality or food compatible. The fermentation apparatus is operated under aeration and maintained at a specified temperature range.

(ii) Purification Process

For product purification, the fermented broth is heated to kill the microorganisms. All the production microorganisms, *Moniella pollinis,* are killed by this treatment.

The concentrated hot erythritol solution is pumped into a crystallizer and cooled to induce crystallization of the product. Alternatively, the crystallization can take place partly or totally during the evaporation process. The crystals are then separated from the mother liquor by centrifugation and washed with demineralized water. The erythritol crystals are then redissolved in demineralized water, and the solution is passed through an ion exchange resin station consisting of an anionic and cationic resin, which is used only for food applications. Additionally, the solution may be decolorized by treatment with activated charcoal. The erythritol solution is then further purified using ultrafiltration (cut-off 5 kD) and crystallized again by cooling or by evaporation. The crystals are centrifuged, washed with demineralized water and dried in a hot air stream, sifted, and packed in bags. The resulting erythritol is at least 99.5% pure.

(iii) Production Microorganism

The production organism, *Moniliella pollinis,* is both non-toxicogenic and non-pathogenic.

(f) Characteristic properties

Erythritol is a naturally occurring four-carbon sugar alcohol, which is the reduced sugar alcohol analogue of the four-carbon monosaccharide, erythrose. Erythritol occurs widely in nature and has been found in to occur naturally in several foods, including wine, sake, beer, mushrooms, watermelon, pears, grapes and soy sauce at levels up to 0.13% (w/v)(Goossens and Röper, 1994; Shindou *et al.*, 1988, 1989). It also exists endogenously in the tissues and body fluids of humans and animals (Goossens and Röper, 1994; Horning *et al.*, 1974; Oku and Noda, 1990; Spencer, 1967).

Erythritol exists as a white, odorless crystal in the form of a tetragonal prism. It is heat stable and non-hygroscopic. Erythritol is also stable under acid and alkaline conditions. It has a melting point of 119 to 123°C, a boiling point of 329-331°C, a heat of fusion of 311-323 J/g and a heat of solution of -180 J/g. It is very soluble in water, slightly soluble in alcohol, and practically insoluble in fats and ether.

Erythritol has a sweetness of about 60-80% that of sucrose, depending on the food in which erythritol is present (Goossens and Röper, 1994). It is noncariogenic (21 C.F.R. § 101.80) and has a caloric value of 0.2 kcal/gram.

(g) Any content of potential human toxicants

None.

(h) Specifications for food-grade material

The specifications for erythritol are as described at pages 10-11 of Food Chemicals Codex IV (Second Supp. 2000) (FCC, 2000).

(2) Information on any self-limiting levels of use

None.

(3) Detailed summary of the basis for the notifier's determination that a particular use of the notified substance is exempt from the premarket approval requirements of the Federal Food, Drug and Cosmetic Act because such use is GRAS

The published scientific literature contains numerous safety studies supporting the safety of erythritol for food use. In October 1996, an Expert Panel of independent experts, qualified by training and relevant national and international experience to

evaluate the safety of foods and food ingredients, conducted a comprehensive and critical review of the available data and information, both published and unpublished, and unanimously concluded that under the conditions of intended use in foods erythritol is GRAS based on scientific procedures (Berndt *et al.*, 1996). The 1996 GRAS determination was confined to more limited uses of erythritol than those that are the subject of this notification. Specifically, the 1996 GRAS determination encompassed use of erythritol in foods (% use levels) as follows: (1) sugar substitutes (100%); (2) hard candies (50%); (3) soft candies (40%); (4) reduced- and low-calorie beverages (1.5%); (5) fat-based cream for use in cookies, cakes, and pastries (60%); (6) dietetic cookies and wafers (7%); and (7) chewing gum (60%) (Berndt *et al.*, 1996). A copy of the published Expert Panel review is enclosed.

In December 1996, Cerestar Holding B.V. (Cerestar), Mitsubishi Chemical Corp., and Nikken Chemicals Co., Ltd. jointly submitted the currently pending GRAS affirmation petition (GRASP 7G0422) for the above-described uses of erythritol. In December 1997, FDA approved a dental health claim for erythritol. *See* 21 C.F.R. § 101.80; *see also* 62 Fed. Reg. 63653 (Dec. 2, 1997).

In 1998, in anticipation of the review of erythritol by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), a second review of the biochemical, metabolic, toxicological, and clinical data, concluding that erythritol was safe for its intended use in foods, was also published (Munro *et al.*, 1998). At its 53rd meeting, JECFA evaluated the safety of erythritol and established an acceptable daily intake (ADI) "not specified" for erythritol for use as a sweetening agent (WHO, 2000a,b). JECFA assigns an ADI "not specified" to substances that, on the basis of the available data, the total dietary intakes resulting from use at levels necessary to achieve the desired effect, and background levels in food, do not represent a hazard to health. Copies of the 1998 Expert Panel review, as well as the 2000 JECFA toxicological monograph and report on erythritol are enclosed.

At the request of Cerestar alone, the Expert Panel reconvened in May 2000 to review the expanded uses of erythritol that are the subject of this GRAS Notification. The Panel concluded that under the conditions of the expanded uses in foods, erythritol meeting appropriate food grade specifications and manufactured in accordance with current good manufacturing practices, is GRAS based on scientific procedures. A copy of the "Expert panel opinion concerning expanded uses of erythritol" is enclosed.

(4) Probable Consumption of the Substance

Erythritol is intended for use as a flavor enhancer, formulation aid, humectant, nutritive sweetener, stabilizer and thickener, sequestrant, and texturizer. As discussed in Section 3 above, the 1996 safety review evaluated erythritol it for use in the following foods: (1) sugar substitutes; (2) hard candies; (3) soft candies; (4) reduced- and low-calorie beverages; (5) fat-based cream for use in cookies, cakes, and pastries; (6) dietetic cookies and wafers; and (7) chewing gum (Berndt *et al.*, 1996). For such uses, the user population mean and 90th percentile intakes were estimated to be 6.9 g/day and 16.9 g/day, respectively. Applying a market share adjustment and assuming that erythritol would replace all xylitol use (20% of total polyol use), a user population mean and 90th percentile consumption of 1g/day and 4 g/day, respectively, was projected.

The expanded uses for erythritol that are the subject of this GRAS Notification require a separate calculation of probable consumption. Exposure calculations estimate the user population mean and 90th percentile intakes to be 14.1 g/day and 30.8 g/day respectively. Applying a market share adjustment and assuming that erythritol would replace all xylitol use (20% of total polyol use), a user population mean and 90th percentile consumption of 4.9 g/day and 11.9 g/day, respectively, corresponding to 0.09 and 0.23 g/k bw/day is projected. Because of their higher food intake relative to body weight, young children aged 1 to 3 years may consume up to 1g/kg bw/day (90th percentile).

(5) Basis for concluding, in light of the data and information described above, that there is consensus among experts qualified by scientific training and experience to evaluate the safety of substances added to food that there is reasonable certainty that the substance is not harmful under the intended conditions of use.

See the enclosed 1996 and 1998 published reviews of the data supporting the GRAS status of erythritol, the 2000 WHO report and toxicological monograph supporting an ADI "not specified" for erythritol, and the May, 2000 "Expert Panel Opinion Concerning Expanded Uses of Erythritol." The Expert Panel that reviewed erythritol consisted of William O. Berndt, Ph.D., University of Nebraska Medical Center, Joseph F. Borzelleca, Ph.D., Medical College of Virginia, W. Gary Flamm, Ph.D., Flamm Associates, and Ian C. Munro, Ph.D., FRCPath, CanTox Health Sciences International.

References

Berndt W.O., Borzelleca J.F., Flamm G., Munro I.C. (1996). Erythritol: a review of biological and toxicological studies. *Regulatory Toxicology and Pharmacology* 24: S191.

Berndt W.O., Borzelleca J.F., Flamm G., Munro I.C. (2000). Expert panel opinion concerning expanded uses of erythritol, May 18, 2000 (unpublished report).

FCC, (2000). Food Chemicals Codex IV (Second Supp. to the Fourth Edition). National Academy Press, Washington DC, pp. 10-11.

Goossens J. and Röper H. (1994). Erythritol: A new bulk sweetener. *International Food Ingredients* 1/2: 27-33.

Horning E.C., Horning M.G., Szafranek J., Van Hout P., German A.L., Thenot J.P. and Pfaffenberger C.D. (1974). Gas phase analytical methods for the study of human metabolites. Metabolic profiles obtained by open tubular capillary chromatography. *Journal of Chromatography* 91, 367-378.

Munro I.C., Berndt W.O., Borzelleca J.F., Flamm W.G., Lynch B.S., Kennepohl E., Bär A., and Modderman J. (1998). Erythritol: an interpretive summary of biochemical, metabolic, toxicological and clinical data. *Food and Chemical Toxicology* 36: 1139-74.

Oku T. and Noda K. (1990). Influence of chronic ingestion of newly developed sweetener, erythritol on growth and gastrointestinal function of the rats. *Nutrition Research* 10, 987-996.

Shindou T., Sasaki Y., Miki H., Eguchi T., Hagiwara K. and Ichikawa T. (1989). Identification of erythritol by HPLC and GS-MS and quantitative measurement in pulps of various fruits. *Journal of Agricultural and Food Chemistry* 37, 1474-1476.

Shindou T., Sasaki Y., Miki H., Eguchi T., Hagiwara K. and Ichikawa T. (1988). Determination of erythritol in fermented foods by high performance liquid chromatography. *Shokuhin Eiseigaku Zasshi* 29, 419-422 (includes English translation).

Spencer N. (1967). Ion exchange chromatography of polyols. *Journal of Chromatography* 30, 566-571.

WHO, (2000a). Sweetening agent: erythritol. In *Evaluation of certain food additives and contaminants.* WHO Technical Report Series 896, §3.2, pp. 18-22. ICPS International Programme on Chemical Safety in Cooperation with the Joint FAO/WHO Expert Committee on Food Additives (JECFA). World Health Organization, Geneva.

WHO, (2000b). Erythritol. In *Safety evaluation of certain food additives and contaminants.* WHO Food Additives Series: 44, pp. 15-70. ICPS International Programme on Chemical Safety in Cooperation with the Joint FAO/WHO Expert Committee on Food Additives (JECFA). World Health Organization, Geneva.

[redacted]

Enclosures

[redacted]

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EXPERT PANEL OPINION CONCERNING EXPANDED USES OF ERYTHRITOL

The undersigned, an independent panel of recognized experts (the "Expert Panel"), qualified by their scientific training and relevant national and international experience in evaluating the safety of food and food ingredients, were requested by Cerestar Holdings BV ("Cerestar") to conduct a comprehensive review of pertinent data and information to determine whether certain expanded uses of erythritol in foods are "generally recognized as safe" ("GRAS") based on scientific procedures. Attached are *curriculum vitae* evidencing the qualifications of the Expert Panel members.

Previously, the safety of erythritol was critically evaluated by the Expert Panel (Bernt *et al.*, 1996). The Panel then concluded that the use of erythritol as a flavor enhancer, formulation aid, humectant, nutritive sweetener, stabilizer and thickener, sequestrant, and texturizer in a number of foods is GRAS based on scientific procedures. For such uses, the Panel estimated the user population mean and 90th percentile intakes to be 6.9 g/day and 16.9 g/day, respectively. Applying a market share adjustment and assuming that erythritol would replace all xylitol use (20% of total polyol use), the Panel projected a user population mean and 90th percentile consumption of 1 g/day and 4 g/day, respectively.

In the course of reviewing the expanded uses of erythritol, the Expert Panel reviewed intake estimates for both the current GRAS uses and the expanded uses combined, the publicly available data and information present in the pending petition for U.S. Food and Drug Administration (FDA) affirmation of the GRAS status of the current uses of erythritol (GRASP 7G0422 submitted jointly by Cerestar Holding Company B.V, Mitsubishi Chemical Corporation and Nikken Chemicals Company, Ltd.), and additional relevant information.

Following independent, critical evaluation of such data and information, the Expert Panel met on May 18, 2000 with representatives of Cerestar. After thorough discussion of the data and information, the Panel concluded that under the conditions of combined current and expanded uses in foods, erythritol meeting appropriate food grade specifications and manufactured in accordance with current good manufacturing practices, is "generally recognized as safe" based on scientific procedures. A summary of the basis for the Panel's conclusion is provided below.

Dietary Exposure

The combined current and expanded uses of erythritol are shown in the attached Table 1. The Panel estimated the user population mean and 90th percentile intakes to be 14.1 g/day and 30.8 g/day, respectively. Applying a market share adjustment and assuming that erythritol would replace all xylitol use (20% of total polyol use), the Panel projected a user population mean and 90th percentile consumption of 4.9 g/day and 11.9 g/day, respectively, corresponding to 0.09 and 0.23 g/k bw/day. Because of their higher food intake relative to body weight, young children aged 1 to 3 years may consume up to 1 g/kg bw/day (90th percentile).

Safety Assessment

Erythritol has been extensively evaluated in a number of toxicological and clinical studies. The preclinical studies include acute, subchronic, chronic, carcinogenicity, reproductive and developmental toxicity, and mutagenicity. High dose effects (e.g., 10% of diet, equivalent to approximately 5 g/kg bw) noted in animal studies such as laxation and diuresis are considered to be physiological responses to osmotic loading, and are not toxicologically significant.

The clinical studies provided information to compare the metabolism and pharmacokinetics of erythritol in humans and animals, and to assess the possibility for the development of effects associated with changes in water balance, both in normal individuals and persons with diabetes. In evaluating the exposures resulting from the current and expanded uses, the Panel considered in particular the potential for laxation, perturbation of renal function, and the possible sensitivity of children.

Transient minor gastrointestinal effects, consisting of loose stools, nausea, gurgling, and flatulence, were reported in the clinical studies after erythritol administration, but only after large acute bolus (liquid) doses and/or administration on an empty stomach. From the studies which evaluated gastrointestinal effects, the laxation threshold for erythritol cannot be clearly defined. However, the data suggest that the laxation threshold is in excess of 0.6 to 0.8 g/kg bw/day under all conditions and is likely greater than 1.0 g/kg bw/day under intended conditions of use. Also, the laxation threshold for erythritol has been reported to be about 4-fold greater than that for sorbitol.

From the clinical studies by Bornet *et al.* (1996a,b) and Tetzloff *et al.* (1996), the threshold for osmotic diuresis can be established. The results of a study in which erythritol was administered in food indicate no overt diuretic effect of a single 0.4 or 0.8 g/kg bw dose (Bornet *et al.*, 1996b). Progressive, statistically significant increases in sodium and chloride excretion and urine osmolality were seen in the study, however, these effects were not accompanied by increased water consumption or increased urinary volume. The increased urinary osmolality could be attributed to the presence of erythritol in the urine. In the Tetzloff *et al.* (1996) repeat dose study, in which human volunteers received 1.0 g/kg bw/day of erythritol in food for 7 days , slight diuresis, in the form of non-significantly increased urine volumes and non-significantly decreased urine electrolyte concentrations were reported. Thus, the threshold for the appearance

of diuretic activity of erythritol under intended conditions of use appears to be in the range of 1.0 g/kg bw/day.

Diuretic effects are due to the increased plasma osmolar load associated with absorbed erythritol. An estimate of the renal capacity required to clear erythritol from the blood to prevent its accumulation can be determined from the available clinical and pharmacokinetic data. Based on the plasma kinetics described for mannitol, and erythritol, a normal healthy 70 kg adult consuming 40 grams of erythritol, would require a maximum of 15 to 25% of normal renal capacity to effectively clear erythritol. Renal function in children aged 1 year and older is essentially equivalent to that of adults when normalized for body weight. Therefore, while young children may experience transient exposures to higher amounts of erythritol because of their higher food intake relative to body weight compared to adults, such exposures would be readily handled by the kidneys.

Detailed analysis of the data provide no evidence to indicate that erythritol, under the conditions of combined current and expanded uses, would be associated with adverse health effects.

Conclusion

Based on our independent and collective critical evaluation of the pertinent data and information, the Expert Panel unanimously concludes that under the conditions of combined current and expanded uses in foods, erythritol meeting appropriate food grade specifications and manufactured and used in accordance with current good manufacturing practices, is "generally recognized as safe" based on scientific procedures.

By:

William O. Berndt, Ph.D. — Date: 18 May 00

Joseph F. Borzelleca, Ph.D. — Date: 18 May 2000

W. Gary Flamm, Ph.D. — Date: May 18, 2000

Ian C. Munro, Ph.D. — Date: May 18/2000

000024

Table 1. Combined Current and Expanded Uses of Erythritol

Food Category	Maximum Level of Erythritol
Bakery fillings (fruit, custard, cream, pudding)	15%
Cakes and cookies (regular and dietetic)	15%
Chewing gum	60%
Dairy drinks (chocolate and flavored milks)	3.5%
Fat-based cream used in modified fat/calorie cookies, cakes and pastries	60%
Hard candies (including pressed candy, mints and cough drops)	99%
Frozen dairy desserts (regular ice cream, soft serve, sorbet)	10%
Puddings (instant, phosphate set)	10%
Reduced- and low calorie carbonated and non-carbonated beverages	3.5%
Soft candies (nonchocolate, plain chocolate, chocolate coated)	60%
Sugar substitutes (carrier)	100%
Yogurt (regular and frozen)	10%

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Pages 000068 - 000097 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

SUBMISSION END

AM

Dietz, Jason

From:
Sent: Tuesday, May 29, 2001 10:00 AM
To: Dietz, Jason
Subject: Fwd: RE: GRAS Notice, ErOH metal contaminants

RE: GRAS Notice, ErOH metal co...

Dear Jason:

I am forwarding to you the below e-mail memo and attachments from Peter de Cock at Cerestar. Please note the Certificates of Analysis appended to Peter's e-mail confirm that the actual lead (Pb) levels in Cerestar's erythritol product are well below 0.1 ppm. The tests show that Pb was not detectable at 0.005 and 0.01 ppm levels.

If the attachments do not transmit properly, or if you have any difficulty opening or printing them, please let me know and I will fax hard copies to you.

If you have any further questions, please do not hesitate to ask.

Yours truly,

Diane McColl
Counsel to Cerestar

****

This e-mail is sent by a law firm and may contain information that is privileged or confidential. If you are not the intended recipient, please delete the e-mail and any attachments and notify us immediately.

****

Diane B. McColl
Hyman, Phelps & McNamara, P.C.
700 Thirteenth St. N.W.
Washington, D.C. 20005

000102

Dietz, Jason

From:
Sent: Tuesday, May 29, 2001 4:28 AM
To: dbm@hpm.com
Subject: RE: GRAS Notice, ErOH metal contaminants


JPEG File Interchange

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Dear Diane,

As evident from the attached analytical certificates of five different batches, the lead (Piombo, Pb) level in Cerestar's erythritol is well below 0.1 ppm (not detectable at 0.005 and 0.01 ppm levels). Please provide these certificates to Jason Dietz at FDA for confirmation.

Congratulations with Elizabeth's graduation! Please pass on my congratulations and greetings to her, Andy and Kathryn.

Kind regards,
Peter

----- Forwarded by Peter DE COCK/VIL/RAD/Cerestar/EBS on 05/29/2001 10:00 -----

Patrizia TOLOMELLI
05/28/2001 14:25

To: Peter DE COCK/VIL/RAD/Cerestar/EBS@EBS
cc:
Subject: ErOH contaminant

Dear Peter,
please find here enclosed CoA for contaminant in erythritol, CoAs are in Italian language Lead is PIOMBO.
I hope these CoAs will be OK for GRAS.
Regards
Patrizia

Patrizia Tolomelli
Quality Assurance Mgr.
Phone 0039 0425 848280
Fax 0039 0425 848239
E-Mail ptolomelli@it.ebsworld.com

(See attached file: METAL1.JPG)
(See attached file: METAL2.JPG)
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(See attached file: METAL4.JPG)
(See attached file: METAL5.JPG)

000103

neotron®

dei Dottor Gian Carlo Gatti
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Modena (Italy), il 04/06/99 Pagina: 1

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CAMPIONE 9E02047

CERTIFICATO DI ANALISI

ERITRITOLO "16952" - 1 CONTENITORE IN PLASTICA - DATA ARRIVO CAMPIONE 17/05/99 -

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METALLI PESANTI					
Berillio come Be	N.R.	mg/kg	0,005		
Cromo come Cr	N.R.	mg/kg	0,005		
Manganese come Mn	N.R.	mg/kg	0,005		
Rame come Cu	N.R.	mg/kg	0,005		
Nichel come Ni	N.R.	mg/kg	0,005		
Zinco come Zn	0,044	mg/kg			
Arsenico come As	N.R.	mg/kg	0,005		
Selenio come Se	N.R.	mg/kg	0,005		
Cadmio come Cd	N.R.	mg/kg	0,005		
Mercurio come Hg	N.R.	mg/kg	0,005		
Piombo come Pb	N.R.	mg/kg	0,005		
Stagno come Sn	N.R.	mg/kg	0,005		
Ferro come Fe	0,046	mg/kg			

Note
N.R.Non rilevabile sperimentalmente

DOTT. GIAN CARLO GATTI Nº 124 — ORDINE DEI CHIMICI — MODENA

[illegible]

neotron CERTIFICAZIONE UNI EN ISO 9001

CERTICHIM CERTIAGRO

EurOchem

Il Chimico
Dott. GIAN CARLO GATTI
[illegible]

000104

neotron
Modena (Italy), li 28/05/97

CERESTAR ITALIA S.p.A.
Via Camatta, 4
45035 CASTELMASSA RO

CAMPIONE 7D01416 PAGINA 1

CERTIFICATO DI ANALISI

Denominazione: ERITRITOLO CAMPIONE MEDIO MESE DI MARZO - 1 CONTENITORE DI PLASTICA -

DESCRIZIONE	VALORE	U.M.	INCERTEZZA	LIMITI	
METALLI PESANTI NEGLI ALIMENTI					
Berillio come Be	N.R.	mg/kg	0,005		
Cromo come Cr	N.R.	mg/kg	0,005		
Manganese come Mn	N.R.	mg/kg	0,005		
Rame come Cu	N.R.	mg/kg	0,005		
Nichel come Ni	N.R.	mg/kg	0,005		
Zinco come Zn	N.R.	mg/kg	0,010		
Arsenico come As	N.R.	mg/kg	0,005		
Selenio come Se	N.R.	mg/kg	0,010		
Cadmio come Cd	N.R.	mg/kg	0,005		
Mercurio come Hg	N.R.	mg/kg	0,005		
Piombo come Pb	N.R.	mg/kg	0,005		
Stagno come Sn	N.R.	mg/kg	0,005		
Ferro come Fe	N.R.	mg/kg	0,050		

Note: N.R. = Non rilevabile sperimentalmente

ORDINE DEI CHIMICI
DOTT. GIAN CARLO GATTI
N. 124
MODENA

CERTIFICATO VALIDO A TUTTI GLI EFFETTI DI LEGGE

Il Direttore
Dott. Gian Carlo Gatti
n. 124

Lo stato di avanzamento delle attività sperimentali della NEOTRON s.r.l.
LABORATORIO CERTIFICATO DAL MINISTERO DELLA SANITÀ in conformità alle buone pratiche di laboratorio, direttiva 88/320/CEE D.L. 27.01.92, N. 120
LABORATORIO AUTORIZZATO D.M. 30.3.87 - ART. 4 - LEGGE 4832 PER LA RICERCA APPLICATA E SPERIMENTAZIONE TECNOLOGICA

000105

neotron

dott. Gian Carlo Gatti
analisi chimiche biochimiche e microbiologiche
[illegible] MODENA
Tel. [illegible] - Fax [illegible]

Modena (Italy), lì 27/10/97

CERESTAR ITALIA S.p.A.
Via Camatta, 4
45035 CASTELMASSA RO

CAMPIONE 7P00822 PAGINA 1

CERTIFICATO DI ANALISI

Denominazione: ERITRITOLO 16952 (ERIDEX) - CAMPIONE MEDIO DEL MESE DI SETTEMBRE

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
METALLI PESANTI NEGLI ALIMENTI					
Berillio come Be	N.R.	mg/kg	0,005		
Cromo come Cr	N.R.	mg/kg	0,005		
Manganese come Mn	N.R.	mg/kg	0,005		
Rame come Cu	N.R.	mg/kg	0,005		
Nichel come Ni	N.R.	mg/kg	0,005		
Zinco come Zn	0,034	mg/kg			
Arsenico come As	N.R.	mg/kg	0,005		
Selenio come Se	N.R.	mg/kg	0,010		
Cadmio come Cd	N.R.	mg/kg	0,005		
Mercurio come Hg	N.R.	mg/kg	0,005		
Piombo come Pb	N.R.	mg/kg	0,005		
Stagno come Sn	N.R.	mg/kg	0,005		
Ferro come Fe	0,258	mg/kg			

Note: N.R. = Non rilevabile sperimentalmente

ORDINE DEI CHIMICI
DOTT. GIAN CARLO GATTI
MODENA

CERTIFICATO VALIDO A TUTTI GLI EFFETTI DI LEGGE [illegible] ARCHIVIAZIONE DATI E CONSERVAZIONE CAMPIONE [illegible]	Il Chimico Dott. GIANCARLO GATTI [illegible]	EurChem

Lo Studio si avvale delle strutture organizzative della NEOTRON s.r.l.
LABORATORIO CERTIFICATO DAL MINISTERO DELLA SANITÀ in conformità alle buone pratiche di laboratorio, [illegible]
LABORATORIO ALTAMENTE QUALIFICATO [illegible] PER LA RICERCA APPLICATA E INNOVAZIONE TECNOLOGICA

000106

neotron
del dr. Gian Carlo Gatti
analisi chimiche, biochimiche e microbiologiche
[illegible]
tel. [illegible] - Fax [illegible]

Modena (Italy), lì 19/05/98

[illegible]
CERESTAR ITALIA S.p.A.
Via Camatta, 4
45035 CASTELMASSA RO

CAMPIONE 8E00610 PAGINA 1

CERTIFICATO DI ANALISI

Denominazione: ERITRITOLO 16892 - CAMPIONE MEDIO MESE DI APRILE 1998 - 1 CONTENITORE IN PLASTICA - DATA ARRIVO CAMPIONE 12.05.98 -

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
METALLI PESANTI NEGLI ALIMENTI					
Berillio come Be	N.R.	mg/kg	0,006		
Cromo come Cr	N.R.	mg/kg	0,005		
Manganese come Mn	N.R.	mg/kg	0,005		
Rame come Cu	N.R.	mg/kg	0,005		
Nichel come Ni	N.R.	mg/kg	0,005		
Zinco come Zn	N.R.	mg/kg	0,010		
Arsenico come As	N.R.	mg/kg	0,005		
Selenio come Se	N.R.	mg/kg	0,010		
Cadmio come Cd	N.R.	mg/kg	0,005		
Mercurio come Hg	N.R.	mg/kg	0,005		
Piombo come Pb	N.R.	mg/kg	0,005		
Stagno come Sn	N.R.	mg/kg	0,005		
Ferro come Fe	0,120	mg/kg			

Note: N.R. = Non rilevabile sperimentalmente

ORDINE DEI CHIMICI * MODENA *
DOTT. GIAN CARLO GATTI
Nº 124

CERTIFICATO VALIDO A TUTTI GLI EFFETTI DI LEGGE [illegible] ARCHIVIAZIONE DATI E CONSERVAZIONE CAMPIONE [illegible]	Il Chimico Dott. GIAN CARLO GATTI [illegible]	EurChem

Lo Studio si avvale delle strutture organizzative della NEOTRON s.r.l.
LABORATORIO CERTIFICATO DAL MINISTERO DELLA SANITÀ [illegible]
LABORATORIO ALTAMENTE QUALIFICATO D.M. 26-2-87 - ART. 4 - LEGGE 46/82 PER LA RICERCA APPLICATA E INNOVAZIONE TECNOLOGICA

000107

Neotron

s.r.l. Dott. Gatti Giancarlo

analisi chimiche biochimiche e microbiologiche

Sede: Via Puccini, 105 - 41058 VIGNOLA (MO)
Telefono (059) 77 42 91 - Fax (059) 76 39 50

LABORATORIO CERTIFICATO DAL MINISTERO DELLA SANITA in conformità alle buone pratiche di laboratorio, direttiva 87/18/CEE
D.L. 27-01-92 N. 120

Vignola 13/05/96 Pag. 2

Spett. CERESTAR ITALIA S.p.A.
Via Gamatta, 4
45030 CASTELMASSA RO

Codice campione 0600686

C E R T I F I C A T O D I A N A L I S I

di un campione denominato: ERITRITOLO (ERIDEX) -
CAMPIONE MEDIO MESE DI FEBBRAIO 1996 -
1 CONTENITORE -

			Limite di Rilevabilità
Mercurio	come Hg	= N.V.	0,010 mg/kg
Tallio	come Tl	= N.V.	0,010 mg/kg
Piombo	come Pb	= N.V.	0,010 mg/kg
Bismuto	come Bi	= N.V.	0,010 mg/kg
Torio	come Th	= N.V.	0,010 mg/kg
Uranio	come U	= N.V.	0,010 mg/kg
Palladio	come Pd	= N.V.	0,010 mg/kg

N.V. = Non valutabile sperimentalmente

ORDINE DEI CHIMICI
DOTT. GIAN CARLO GATTI
Nº 184
MODENA

Il Chimico
Dott. GIANCARLO GATTI

CERTIFICATO VALIDO A TUTTI GLI EFFETTI DI LEGGE ai sensi dell'art. 16 R.D. 1-3-1928 n. 842 - artt. 15 e 16 Legge 19-7-1957 n. 679 - D.M. 21-6-1970 - art. 6 e 8 D.M. 25-3-1986

ARCHIVIAZIONE DATI E CONSERVAZIONE CAMPIONE [illegible]

AUTORIZZAZIONE DEL MINISTERO DELL'AGRICOLTURA E DELLE FORESTE ALLA CERTIFICAZIONE DEI VINI PER L'ESPORTAZIONE
LABORATORIO ALTAMENTE QUALIFICATO D.M. 26-2-87 - ART. 4 - LEGGE 46/82 PER LA RICERCA APPLICATA E INNOVAZIONE TECNOLOGICA

000108

AM

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(1945-1996)

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BRIAN J. MALKIN

*NOT ADMITTED IN DC

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FROM:	Diane B. McColl	**DATE:**	June 8, 2001
TO:	Jason Dietz	**FAX NO.:**	202-418-3131

NO. OF PAGES (including this page): 2

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(1945-1996)

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BRIAN J. MALKIN

*NOT ADMITTED IN DC

June 8, 2001

BY FACSIMILE/CONFIRMATION BY MAIL

Jason Dietz
Consumer Safety Officer
Office of Premarket Approval (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street S.W.
Washington, D.C. 20204

Re: Erythritol GRAS Notice (GRN 76)

Dear Jason:

As recommended, Cerestar Holding B.V. has reduced its internal specification for the lead (Pb) content of erythritol from 1.0 ppm to 0.1 ppm. All other erythritol specifications will remain as stated in the current *Food Chemicals Codex IV* monograph.

If you have any further questions concerning the erythritol GRAS notice, please do not hesitate to call.

Sincerely,

Diane B. McColl
Counsel to Cerestar Holding B.V.

DBM/dmh

000110

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BRIAN J. MALKIN

*NOT ADMITTED IN DC

July 16, 2001

BY FACSIMILE/CONFIRMATION BY MAIL

Jason Dietz
Consumer Safety Officer
Office of Premarket Approval (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street S.W.
Washington, D.C. 20204

Re: Erythritol GRAS Notice (GRN 76)

Dear Jason:

As requested during our conference call on June 28, 2001, enclosed is a detailed explanation and supporting documentation for the estimated intake analysis conducted by the Expert Panel and described in Cerestar Holding B.V.'s GRAS notice for erythritol.

If you have any further questions concerning the erythritol GRAS notice, please do not hesitate to call.

Sincerely,

Diane B. McColl
Counsel to Cerestar Holding B.V.

DBM/dmh
Enclosure

000112

2603 MAIN STREET
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July 12, 2001

Diane B. McColl
Partner
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W. Suite 1200
Washington, DC 20005

Dear Ms. McColl:

We, as members of the Expert Panel on Erythritol, have been asked to provide further details as to the Panel's assumptions regarding application of the market share adjustment to the estimated intake analysis described in the GRAS opinion dated May 18, 2000, "Expert Panel Opinion Concerning Expanded Uses of Erythritol". Enclosed is a detailed report summarizing the basis for the market share assumption and outlining the calculations that support the GRAS opinion statement that the mean and 90th percentile user intakes would be expected not to exceed 4.9g/day and 11.9g/day respectively.

In deriving the market share adjustment, the Panel used the same philosophical approach outlined in a memorandum dated May 23, 1995 from Dr. M. Di Novi to Dr. L. Tarantino supporting application of a market share adjustment to the estimated intake analysis for Sucrose Fatty Acid Esters. Specifically, the Panel considered the following points:

- Erythritol and xylitol share similar physical and chemical properties (*i.e.* cooling effects) and thus it was assumed that the market currently occupied by xylitol would be completely replaced by erythritol.

- Recent surveys of polyol use from the UK indicate that xylitol occupies about 10% of the market share for polyols. The Panel used a figure of 20% of the total polyol market in calculating the intake for erythritol.

- The Panel applied the market share adjustment to regular and dietetic foods in which polyols are currently in use. For the food categories in which polyols are not currently used, including carbonated and non-carbonated beverages and dairy drinks, the Panel assumed that erythritol was the sole bulk sweetening agent in use.

- While the Panel did not incorporate any correction for the nature of food intake data from the USDA (1989-1991) survey used to calculate erythritol intakes, the Panel recognized that the estimated erythritol intakes were based on 3-day survey data which would overestimate chronic intake. Data from a recent European survey indicate that food

intake estimated from 14 day data is approximately half that estimated from 3-day data. These data suggest that the erythritol intakes are overestimated by at least a factor of two.

- The manufacturer of erythritol, Cerestar, has indicated that erythritol is much more expensive than the other polyols which would limit its application to foods where its functionality would justify the cost.

- If the assumption is made that erythritol is consumed by 10% of the population at a mean intake of 5 g/day, the annual poundage derived by summing intakes for this segment of the population is roughly equivalent to the total of all polyol poundage based on the 1987 NAS survey.

Based on the above, the Expert Panel concluded that the estimates of erythritol intake presented in the GRAS opinion are highly conservative. We believe that application of the market share adjustment to the estimated intake analysis for erythritol is entirely appropriate and fully supported by the well-defined characteristics of the mature polyol market.

If you have any further questions regarding the intake analysis adopted by the Expert Panel, we would be pleased to discuss them with you.

Yours sincerely,

Ian Munro, Ph.D., F.A.T.S., FRCPath

Gary Flamm, Ph.D., F.A.C.T, F.A.T.S.

CANTOX
HEALTH SCIENCES INTERNATIONAL

ESTIMATED CONSUMPTION OF ERYTHRITOL FROM PROPOSED EXPANDED USE PROFILE[1]

Prepared for:

Cerestar Holding BV
Havenstraat 84
1800 Vilvoorde
Belgium

Prepared by:

CANTOX HEALTH SCIENCES INTERNATIONAL
2233 Argentia Road, Suite 308
Mississauga, Ontario, Canada
L5N 2X7

July 16, 2001

[1] ***Excerpt of Data and Information from "Documentation Supporting the Generally Recognized as Safe (GRAS) Status for the Proposed Expanded Use Profile of Erythritol" (Dated May 5, 2000)***

CANTOX Offices:

Mississauga	*Vancouver*	*New Jersey*
905-542-2900	*604-688-8255*	*908-429-9202*

ESTIMATED CONSUMPTION OF ERYTHRITOL FROM PROPOSED EXPANDED USE PROFILE

Table of Contents

List of Tables

ESTIMATED CONSUMPTION OF ERYTHRITOL FROM PROPOSED EXPANDED USE PROFILE

1.0 INTRODUCTION

Erythritol is a four-carbon sugar alcohol (polyol) intended for use in various foods as a low calorie sweetener. It has a sweetness 60 to 80% that of sucrose. Erythritol is produced by a glucose fermentation process using safe and suitable osmophilic yeasts, either *Moniliella pollinis* or *Trichosporonoides megachliensis*. Once erythritol is separated from the fermentation broth, it is purified to result in a crystalline product that is more than 99% pure.

In 1996, the safety of erythritol was extensively reviewed by an Expert Panel (Bernt *et al.*, 1996; Munro *et al.*, 1998) convened jointly by Cerestar Holding Company BV, Mitsubishi Chemical Corporation and Nikken Chemicals Company, Ltd., to determine its status with respect to being Generally Recognized as Safe (GRAS) for use in food. This subsequently led to the acceptance for filing of a GRAS affirmation petition (FDA, 1997) submitted jointly by the three companies. More recently, the Joint FAO/WHO Expert Committee on Food Additives (JECFA), following critical review of the supporting toxicology and clinical data, assigned an acceptable daily intake (ADI) of "not specified" (JECFA, 2000). This applies to "*substances of very low toxicity which, on the basis of the available data (chemical, biological, toxicological, and other), the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food does not, in the opinion of JECFA, represent a hazard to health*" (JECFA, 1996).

The1996 GRAS and the 2000 JECFA decision apply to the intended use of erythritol as a flavor enhancer, formulation aid, humectant, nutritive sweetener, stabilizer and thickener, sequestrant, and texturizer at maximum levels of 100% in sugar substitutes (carrier); 50% in hard candies; 40% in soft candies (mint flavored and chocolates); 1.5% in reduced- and low-calorie noncarbonated beverages; 60% in fat-based cream for use in modified fat/calorie cookies, cakes and pastries; 7% in dietetic cookies and wafers, and; 60% in chewing gum. Based on these use categories and assuming that erythritol would replace all xylitol use (20% of total polyol use), the projected user population mean and 90th percentile consumption was found to be 1 g and 4 g/day, respectively. Replacement of all polyols gave projected population user mean and 90th percentile intakes of 5 g and 20 g/day. These 90th percentile projected intakes correspond to dosages of 0.06 and 0.3 g/kg body weight/day, respectively.

As a result of technical advances in formulating food products, Cerestar Holding Co. BV reconvened the Expert Panel to evaluate the expanded uses of erythritol which include five new

food categories including bakery fillings, dairy drinks, frozen dairy desserts (ice cream), puddings and yogurt. In addition, a number of the established categories have been modified, for example, dietetic cookies have been expanded to included regular and dietetic cakes and cookies at a higher use level, reduced and low calorie beverages have been expanded to include carbonated and noncarbonated beverages at a higher use level, the use level in hard candies has been raised, and the use in soft candies has been expanded to include all soft candy types at higher use levels. The current food categories and expanded food categories are summarized in Table 1-1.

Table 1.0-1 Current and Expanded Erythritol Food Categories

Current Food Categories	Expanded Food Categories
Chewing gum	Bakery fillings (fruit, custard, cream, pudding)
Cookies and wafers	Cakes and cookies (regular and dietetic)
Fat-based cream used in modified fat/calorie cookies, cakes and pastries	Chewing gum
Hard candies	Dairy drinks (chocolate and flavored milks)
Reduced- and low calorie beverages	Fat-based cream used in modified fat/calorie cookies, cakes and pastries
Soft candies	Frozen dairy desserts (regular ice cream, soft serve, sorbet)
Sugar substitutes (carrier)	Hard candies (including pressed candy, mints and cough drops)
	Puddings (instant, phosphate set)
	Reduced- and low calorie carbonated and non-carbonated beverages
	Soft candies (nonchocolate, plain chocolate, chocolate coated)
	Sugar substitutes (carrier)
	Yogurt (regular and frozen)

Based on this expanded use pattern, the projected users mean and 90th percentile consumption for the total population assuming a 20% marketshare (for categories other than beverages) based on technical similarities to xylitol are in the range of 4.9 and 11.9 grams per day, respectively.

This report documents the estimated erythritol consumption from previous categories of use in addition to the estimated erythritol consumption from its expanded use profile.

2.0 CONSUMPTION ESTIMATES FROM PROPOSED ERYTHRITOL FOOD USES

There are a number of different methods available for estimating the consumption of food ingredients. These range from 1) per capita methods, either from production data or determined from food disappearance data tabulated by respective governments; 2) methods that use available food consumption databases; to 3) actual specific food ingredient consumption surveys. Each of these methods has advantages and disadvantages (Anderson, 1988, Löwik, 1996).

Per capita methods include food ingredient consumption estimations determined from the disappearance of specific food commodities containing the food ingredient or determinations from actual production data of the food ingredient. Although per capita methods provide a representative general population mean of food ingredient consumption, they cannot provide consumption estimates for specific segments of the population. This may include populations that consume exceptionally high amounts of particular foods, either as a function of age, health status or choice (Lauer and Kirkpatrick, 1991).

Food consumption survey methods vary in their design and collection of dietary intake data can range from 24-hour dietary recalls to multi-day dietary records. It is well known that short-term food consumption data do not represent 'usual' intake over a longer time period. Twenty-four hour dietary recall data have been found to overestimate consumption of specific food components of both the all-persons group and the specific users or eaters of specific food products (Lauer and Kirkpatrick, 1991). In addition, these types of surveys are generally considered to be 'worst case' as a result of several conservative assumptions made in estimating consumption. For example, it is often assumed that all food products within a food category contain the ingredient at the maximum level of use. Because of significant intra-person variability in food consumption, food consumption does not follow a normal distribution and it is difficult to accurately determine the consumption of individuals at the upper spectrum of consumption or those individuals in the 90^{th} to 99^{th} percentile. The greater the length of the dietary survey, the more accurate are the consumption estimates of consumers at the extremes of consumption.

Actual surveys of food ingredients following establishment of these ingredients in the market place give the most accurate consumption estimates since they are based on the consumption of specific brands of food products that contain the ingredient in question and are based on the actual concentration of the ingredient in the product. They also can provide good representative estimations of special population groups.

2.1 Previous Erythritol Consumption Estimates

2.1.1 Current Food Uses and Use Levels

In the United States, erythritol is used as a flavor enhancer, formulation aid, humectant, nutritive sweetener, stabilizer and thickener, sequestrant, and texturizer. The levels of use and foods in which it is used are summarized in Table 2.1.1-1.

Table 2.1.1-1 Current Food Categories and Levels of Use of Erythritol

Food Category	Maximum Level of Erythritol
Chewing gum	60%
Cookies and wafers	7%
Fat-based cream used in modified fat/calorie cookies, cakes and pastries	60%
Hard candies	50%
Reduced- and low calorie beverages	1.5%
Soft candies	40%
Sugar substitutes (carrier)	100%

2.1.2 Erythritol Consumption Estimates

Based on the food uses and levels summarized in Table 2.1.1-1 and the USDA Continuing Survey of Food Intake By Individuals (USDA CSFII, 1989-91), the estimated consumption of erythritol by different population groups within the United States is summarized in Table 2.1.2-1. These data do not include the erythritol consumption from chewing gum that was determined from a separate survey.

Table 2.1.2-1 Estimated Erythritol Consumption by Different Population Groups Using UDSA CSFII 1989-91

Population Group	% Users	All-Person Consumption g/day (mg/kg bw/day)		All-Users Consumption g/day (mg/kg bw/day)	
		Mean	90th Percentile	Mean	90th Percentile
Total population	22.6	1.36 (26)	4.63 (78)	6.02 (115)	14.51 (264)
Male and Females Aged 0-12 Years	18.5	1.07 (46)	3.55 (140)	5.77 (250)	13.88 (594)
Male and Females Aged 13-18 Years	20.6	1.89 (32)	6.59 (114)	9.18 (156)	17.18 (326)
Male and Females Aged 19-65 Years	23.2	1.45 (21)	4.92 (69)	6.22 (88)	15.12 (216)

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Since data derived from USDA CSFII and the separate chewing gum survey cannot be directly combined, the data was first normalized based on the contribution of chewing gum to the total consumption estimates (see Appendix A). The consumption of erythritol from chewing gum by either children or adults was essentially the same with mean consumption by users of 4.13 g/day with a 90th percentile consumption of 8.10 g/day. For the total population group, inclusion of chewing gum raised the mean erythritol consumption from 6.02 g/day to 6.90 g/day and raised the erythritol consumption of heavy consumers from 14.51 g/day to 16.85 g/day.

Considering that the above methodology represents 'worst case' consumption estimates as previously discussed, better estimates of expected erythritol consumption were based on actual surveys of polyol consumption in Europe. Total polyol consumption in the United Kingdom in diabetics based on a 4-day dietary survey indicated median intakes of 4.1 g/day with heavy user intakes (97.5th percentile) of 27.6 g/day (MAFF, 1990). At the time of this study, only sorbitol, mannitol and xylitol were available in food products. In another study, the mean consumption of total polyols in Finnish diabetics was 5.7 g/day based on a 2-day survey (Virtanen *et al.*, 1988). Sorbitol and xylitol were well established in the Finnish market at this time and these two polyols were consumed in proportions of 80/20, respectively.

Considering that multiple polyols including sorbitol, xylitol, isomalt, maltitol, maltitol syrup, lactitol, mannitol and hydrogenated starch hydrolysates are currently marketed in similar food types with sorbitol being the predominant polyol, then it is unlikely that erythritol will obtain a 100% marketshare. The technical properties of xylitol and erythritol are similar in that they both result in a cooling effect upon consumption, therefore erythritol may possibly obtain a similar marketshare of up to 20% (based on Finnish data) of the total polyol market. Therefore, the expected mean erythritol consumption based on current total polyol consumption in the United Kingdom would approximate 1 g/day with heavy consumers intake of 4 g/day. These estimated consumption values are similar to that derived from the USDA CSFII 1989-91 following correction for 20% marketshare, mean consumption of 1.4 g/day and 90th percentile consumption of 3.4 g/day.

2.2 Erythritol Consumption Estimates from Current and Expanded Food Uses

2.2.1 Expanded Food Uses and Use Levels

As a result of technical advances, erythritol has been found to be useful in a number of additional food types. In addition, the use level in a number of previous food types has been increased as a result of additional research into various food formulations. The new proposed food categories and use levels are summarized in Table 2.2.1-1.

Table 2.2.1-1 Current and Expanded Food Categories and Levels of Use for Erythritol	
Food Category	Maximum Level of Erythritol
Bakery fillings (fruit, custard, cream, pudding)	15%
Cakes and cookies (regular and dietetic)	15%
Chewing gum	60%
Dairy drinks (chocolate and flavored milks)	3.5%
Fat-based cream used in modified fat/calorie cookies, cakes and pastries	60%
Hard candies (including pressed candy, mints and cough drops)	99%
Frozen dairy desserts (regular ice cream, soft serve, sorbet)	10%
Puddings (instant, phosphate set)	10%
Reduced- and low calorie carbonated and non-carbonated beverages	3.5%
Soft candies (nonchocolate, plain chocolate, chocolate coated)	60%
Sugar substitutes (carrier)	100%
Yogurt (regular and frozen)	10%

Several new categories such as bakery fillings, dairy drinks, frozen dairy desserts (ice cream), puddings and yogurt have been added whereas a number of the established categories have been modified. For example, dietetic cookies have been expanded to included regular and dietetic cakes and cookies at a higher use level, reduced and low calorie beverages have been expanded to include carbonated and noncarbonated beverages at a higher use level, the use level in hard candies has been raised, and the use in soft candies has been expanded to include all soft candy types at higher use levels.

2.2.2 Comparison of Erythritol Uses and Use Levels to Those of Other Polyols

A number of other polyol products such as hydrogenated starch hydrolysates, isomalt, lactitol, maltitol, maltitol syrup, mannitol, sorbitol, and xylitol are currently marketed in the United States. Although several of these materials are restricted to uses such as hard and soft candy, and chewing gum at similar use levels proposed for erythritol, both isomalt and sorbitol have a large range of proposed uses which encompass all erythritol uses and use levels with the exception of beverage use. Specific uses of various polyols are summarized in Appendix B.

2.2.3 Erythritol Consumption Estimates Using USDA CSFII

Based on the expanded list of erythritol uses and use levels, and the USDA CSFII 1989-1991, revised erythritol consumption estimates were determined and are summarized in Table 2.2.3-1. Details of food codes used to generate the total consumption estimates and the consumption estimates for individual food categories are presented in Appendix C.

Table 2.2.3-1 Estimated Erythritol Consumption by Different Population Groups from Current and Expanded New Uses Using USDA CSFII 1989-91

Population Group	% Users	All-Person Consumption g/day (mg/kg bw/day)		All-Users Consumption g/day (mg/kg bw/day)	
		Mean	90th Percentile	Mean	90th Percentile
Total population	75.2	10.1 (194)	25.9 (481)	13.4 (258)	29.2 (561)
Male and Females Aged 0-12 Years	75.6	8.8 (371)	23.0 (961)	11.7 (490)	26.2 (1130)
Male and Females Aged 1-3 Years	72.1	5.6 (429)	17.8 (1340)	8.8 (595)	20.6 (1410)
Male and Females Aged 13-18 Years	81.6	11.7 (201)	29.0 (490)	14.3 (246)	32.0 (569)
Male and Females Aged 19-65 Years	73.6	10.6 (148)	27.2 (384)	14.4 (200)	31.5 (438)

As a result of significantly increasing the number of proposed uses, the percent users increased over 3-fold from that previously determined using this methodology. Considering that the number of users is relatively large, there is little difference in the all-person consumption estimates and the all-user consumption. The expanded food uses and modified resulted in an approximate doubling of the estimated erythritol consumption determined previously using this methodology. The largest estimated intakes occurred in male and females aged 13 to 18 years with mean user estimated intakes of 14.3 g/day (90th percentile - 32.0 g/day). On a body weight basis, the largest mean estimated intakes occurred in males and females aged 0 to12 years, 0.49 g/kg body weight/day (90th percentile -1.13 g/kg body weight/day), and subsequently in males and females aged 1 to 3 years, 0.6 g/kg body weight/day (90th percentile - 1.41 g/kg body weight/day).

2.2.4 Impact of Chewing Gum Uses on Erythritol Consumption

Since it is known that addition of consumption estimates on a users category basis leads to large overestimates of consumption and chewing gum intake estimates were determined in a separate survey, the impact of chewing gum on the total erythritol consumption estimates can only be determined by normalization of the chewing gum estimates (see Appendix A). Because of the increase in the number of food categories, the addition of chewing gum erythritol consumption makes less impact on the total erythritol consumption estimates than was determined in the original GRAS review. For the total population group, inclusion of chewing gum raised the mean erythritol consumption from 13.40 to 14.13 g/day and raised the erythritol consumption of heavy consumers from 29.20 to 30.80 g/day.

2.2.5 Impact of Food Consumption Survey Length on Erythritol Consumption

It is well established that the length of a dietary survey affects the estimated consumption of individual users. Short-term surveys, such as the typical 3-day dietary survey, overestimate consumption over longer time periods (greater than 3 months) that are more appropriate to safety assessments (Anderson, 1988). The impact of survey length on consumption of individual food products by users varies given their frequency of use. For foods such as bread, which are typically consumed on a daily basis, a 3-day survey likely approximates long-term user consumption. For other foods that are consumed less frequently, longer time periods are required to establish long-term user consumption.

The impact of the length of dietary surveys on the user consumption of different types of food products has recently been studied (Institute of European Food Studies, 1998). In this multi-country study, the consumption of 32 food types including carbonated soft drinks and candy was examined in 1,000 males and females aged 10 to 18 years in a food diary study for 1, 3, 5, 7, 10, and 14 days. In general, the mean consumption of users decreased over the length of the study depending on the food type (see Table 2.2.5-1).

Table 2.2.5-1 Effect of Food Consumption Survey Length on User Consumption of Different Food Types

Food Product	Users 3-Day Consumption		Users 14-Day Consumption		Ratio of 3-Day/14-Day Consumption	
	Mean (g/day)	90th Percentile (g/day)	Mean (g/day)	90th Percentile (g/day)	Mean	90th Percentile
Biscuits (cookies)	29	64	16	42	1.8	1.5
Carbonated sugar-free soft drinks	203	502	77	172	2.6	2.9
Hard candy (sweets)	20	55	12	31	1.7	1.8
Ice cream	40	76	18	39	2.2	2.0
Soft candy (chocolate)	31	70	21	48	1.5	1.5
Yogurt	104	200	55	121	1.9	1.7

The average decrease in the mean or 90th percentile consumption is approximately 1.9- to 2-fold. Thus, the estimates of chronic consumption presented in Table 2.2.3-1 are overestimated by approximately 2-fold. The mean chronic consumption of erythritol in the children's category (ages 0 to 12 years) that represents the largest estimated consumption on a body weight basis would approximate 5.7 g/day or 0.25 g/kg body weight/day (90th percentile - 13.1 g/day or 0.55 g/kg body weight/day). Subsequently in children aged 1 to 3 years, the mean chronic erythritol

consumption would approximate 4.4 g/day or 0.3 g/kg body weight/day (90th percentile - 10.3 g/day or 0.7 g/kg body weight/day).

2.2.6 Marketshare Considerations

Assuming that all food products within a specific category would be formulated with erythritol ignores the fact that different manufacturers of similar food products would incorporate different polyols and use different concentrations in their products. Although consumers may choose a specific product type from a specific manufacturer as a result of preference, consumers would not consume the same polyol across other product categories. Therefore, the above values represent serious overestimations of consumption.

A more realistic estimate of consumption can be determined by adjusting the above estimates for marketshare. In the 1997 GRAS affirmation petition, the estimates were adjusted on the basis that erythritol is technically similar to xylitol (*e.g.*, mouth cooling effect, low hygroscopicity) and would be expected to have a similar market share. Xylitol was estimated to make up a maximum of 20% of the total polyol market which is dominated by sorbitol based on older food ingredient surveys in Europe where sorbitol, mannitol and xylitol consumption were surveyed. Newer information regarding the marketshare of different polyols is available (MAFF, 1997) which includes new consumption information for sorbitol, mannitol, xylitol, isomalt, maltitol syrup, and lactitol. Based on this information, xylitol consumption accounts for approximately 10% of the total polyol market and thus 20% marketshare is still a conservative estimate of the potential market.

Erythritol and all other polyols are used in similar food categories like soft and hard candy, frozen dairy desserts, and chewing gum, *etc.* and thus compete in the marketplace. The two exceptions are the proposed use of erythritol in canned/bottled carbonated and non-carbonated soft drinks and dairy beverages in which other polyols are not used.

The consumption estimates discussed in the Table 2.2.3-1 were modified by adjusting the intake estimates for marketshare in food categories for which erythritol would compete with other polyols but not taking marketshare into account for beverages.

For example, following removal of the canned/bottled carbonated and non-carbonated soft drinks, and dairy beverage categories from the consumption totals, the mean consumption estimates for users in the total population was determined to be 10.2 g/day with heavy consumer estimates (90th percentile) of 23.0 g/day (see Appendix D). Adjusting these values on the basis of a 20% marketshare results in mean and 90th percentile consumption estimates of 2.04 and 4.60 g/day, respectively.

From research conducted on dietary survey approaches, it is known that the addition of a series of ingredient estimates from different food categories for users will result in an unrepresentative overestimation of ingredient intake. Therefore, the consumption estimates of canned/bottled carbonated and non-carbonated soft drinks, and dairy beverages cannot be added directly to the consumption estimates derived from the other categories that were adjusted for marketshare.

As an approximation of total consumption, the consumption estimates from the two different estimates were "normalized" to obtain a projected consumption of erythritol that included a marketshare adjustment in food categories in which other polyols were used and a non-adjusted value from consumption of canned/bottled carbonated and noncarbonated soft drinks, and dairy beverages in which other polyols are not used. In order to do this, the all-users erythritol consumption estimates from all individual food categories (except canned/bottled noncarbonated and carbonated soft drinks, and dairy beverages) were added. This total is then adjusted for marketshare (20%) and used as the denominator to derive a theoretical percent contribution that each of the food categories would contribute to the correct users intake. The all-users intake of erythritol from canned/bottled carbonated and noncarbonated soft drinks, and dairy beverages is added to this corrected individual total and used to derive a normalization factor to adjust the consumption value derived from food categories other than canned/bottled carbonated and noncarbonated soft drinks, and dairy beverages for the additional consumption of erythritol from canned/bottled carbonated and noncarbonated soft drinks, and dairy beverages.

The estimated erythritol consumption in different population groups following marketshare correction is summarized in Table 2.2.6-1. Details of the calculations are given in Appendix D. Estimates on a body weight basis were determined on a proportional basis from Table 2.2.3-1. The marketshare corrections were based on the 3-day food consumption data and not from estimates based on corrections for longer-term consumption (*e.g.*, 14 days).

Table 2.2.6-1 Estimated Erythritol Consumption by Different Population Groups from Current and Expanded Uses Using USDA CSFII 1989-91 and Corrected for Marketshare Considerations

Population Group	% Users	All-Users Consumption g/day (mg/kg bw/day)	
		Mean	90th Percentile
Total Population	75.2	4.85 (93)	11.86 (228)
Male and Females Aged 0-12 Years	75.6	4.16 (174)	9.49 (409)
Male and Females Aged 1-3 Years	72.1	4.14 (280)	12.67 (867)
Male and Females Aged 13-18 Years	81.6	6.73 (116)	16.59 (295)
Male and Females Aged 19-65 Years	73.6	5.27 (73)	11.49 (160)

Following adjustment for marketshare considerations, male and females users aged 13 to 18 years would consume the largest amounts of erythritol with mean estimated erythritol intakes of 6.73 g/day whereas heavy consumers (90th percentile) may consume 16.59 g/day. On a body weight basis, male and female users aged 0 to 12 years would consume the largest amounts of erythritol with mean estimated erythritol intakes of 0.17 g/kg body weight/day whereas heavy consumers (90th percentile) may consume 0.41 g/kg body weight/day. Subsequently, male and female users aged 1 to 3 years would have mean estimated erythritol intakes of 0.28 g/kg body weight/day whereas heavy consumers (90th percentile) may consume 0.87 g/kg body weight/day.

3.0 SUMMARY AND CONCLUSIONS

There are a number of different methods for estimating the consumption of food ingredients, the most accurate of which include specific ingredient consumption surveys. This method is the most accurate as a result of the use of specific ingredient levels in specific products manufactured by individual manufacturers. These types of surveys are usually done following establishment of the specific ingredients and foods in the marketplace and take into account technical differences in ingredients and consumer preferences.

Other methods using short term food consumption surveys, such as the United States Department of Agriculture Continuing Survey of Food Intake By Individuals (USDA CSFII), are

recognized as providing worst case chronic consumption estimations because they assume that all proposed food products manufactured by different manufacturers would contain the ingredient at the highest proposed use level. In effect, they assume that the new ingredient would replace all similar technically functional ingredients in the marketplace. In this case, it assumes that erythritol would replace all other polyols currently marketed in the United States.

Erythritol is technically similar in functionality to xylitol (*e.g.*, mouth cooling effect, low hygroscopicity) and would be expected to have a similar market share. Xylitol is well established in the European market along with most other polyols currently marketed in the United States. Based on recent European surveys, xylitol was considered to make up a conservative 20% of the total polyol market. Although all other polyols are used in similar products as erythritol, other polyols are not used in beverage formulations. Therefore, erythritol will not compete with other polyols in beverage market. Correction of the worst-case erythritol consumption estimates on the basis of the expected 20% marketshare results in erythritol consumption estimates summarized in Table 3.0-1.

Table 3.0-1 Summary of Estimated Erythritol Consumption by Different Population Groups from Current and Expanded Uses Using USDA CSFII 1989-91 and Corrected for Marketshare Considerations

Population Group	All-Users Consumption (g/day)		All-Users Consumption (mg/kg bw/day)	
	Mean	90th Percentile	Mean	90th Percentile
Total population	4.85	11.86	93	228
Male and Females Aged 0-12 Years	4.16	9.49	174	409
Male and Females Aged 1-3 Years	4.14	12.67	280	867
Male and Females Aged 13-18 Years	6.73	16.59	116	295
Male and Females Aged 19-65 Years	5.27	11.49	73	160

Male and females users aged 13 to 18 years would consume the largest amounts of erythritol with mean estimated erythritol intakes of 6.73 g/day whereas heavy consumers (90th percentile) may consume 16.59 g/day. On a body weight basis, male and female users aged 0 to12 years would consume the largest amounts of erythritol with mean estimated erythritol intakes of 0.17 g/kg body weight/day whereas heavy consumers (90th percentile) may consume 0.41 g/kg body weight/day. Subsequently, male and female users aged 1 to 3 years would have mean estimated erythritol intakes of 0.28 g/kg body weight/day whereas heavy consumers (90th percentile) may consume 0.87 g/kg body weight/day.

The above consumption estimates were determined on the basis of 3-day consumption data corrected for a 20% marketshare. Considering the impact of survey length on chronic consumption estimates, the consumption estimates discussed in the proceeding paragraph are likely overestimated by approximately a factor of 2. Thus, chronic consumption estimates may be expected to be less than that described above.

Current consumption of other polyols based on a specific survey of bulk sweeteners in diabetics (MAFF, 1997) indicates that the mean users consumption of individual polyols ranges from 0.1 to 0.9 g/day to maximum intakes of 3.1 to 13.8 g/day, excluding uses of sorbitol. The marketshare corrected consumption estimates for erythritol would fall into the same range.

All of the adjusted erythritol chronic consumption estimates are below those levels that may result in physiological effects in humans.

4.0 REFERENCES

Anderson, S.A. (Ed.). 1988. Estimation of Exposure to Substances in the Food Supply. Federation of American Societies for Experimental Biology (FASEB), Life Science Research Office (LSRO), Bethesda, MD.

Bernt, W.O., Borzelleca, J.F., Flamm, G., and Munro, I.C. 1996. Erythritol: A review of biological and toxicological studies. Regul Toxicol Pharmacol 24(2, Prt. 2):S191-S197.

FDA. 1997. Cerestar Holding Co. B.V., Mitsubishi Chemical Corp., and Nikken Chemicals Co., Ltd.; Filing of petition for affirmation of GRAS status. Fed Reg (U.S.) 62(44):10285.

Institute of European Food Studies. 1998. The Effect of Survey Duration on the Estimation of Food Chemical Intakes. pp. 1-78.

JECFA. 1996. Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) 1956-1995 (first through forty-fourth meetings). Food and Agricultural Organization of the United Nations, Rome. World Health Organization, Geneva.

JECFA 2000. Evaluation of Certain Food Additives and Contaminants, WHO Technical Report Series, No.896. Fifty-third Report of the Joint FAO/WHO Expert Committee on Food Additives. World Health Organization, Geneva.

Lauer, B.H., and Kirkpatrick, D.C. 1991. Food Additive Intake: Estimated Versus Actual. In: MacDonald, I. (Ed.) Monitoring Dietary Intakes. Chapter 15. Springer-Verlag, Berlin. pp. 170-182.

Löwik, M.R.H. 1996. Possible use of food consumption surveys to estimate exposure to additives. Food Addit Contam 13:427-441.

MAFF 1990. Intakes of Intense and Bulk Sweeteners in the UK, 1987-1988. Twenty-ninth Report of the Steering Group on Food Surveillance. Food Surveillance Paper No. 29. UK Ministry of Agriculture, Fisheries and Food (MAFF), London, UK.

MAFF 1997 (unpublished). Intakes of Intense and Bulk Sweeteners by Diabetics in the UK, 1994-1995. UK Ministry of Agriculture, Fisheries and Food (MAFF), London, UK.

Munro, I.C., Bernt, W.O., Borzelleca, J.F., Flamm, G., Lynch, B.S., Kennepohl, E., Bar, E.A. and Modderman, J. 1998. Erythritol: An interpretive summary of biochemical, metabolic, toxicological and clinical data. Food Chem Toxicol 36:1139-1174.

U.S. Department of Agriculture (USDA). 1996. Nationwide Food Consumption Survey: 1989-91 Continuing Survey of Food Intakes by Individuals (CSFII), and Diet and Health Knowledge Survey (DHKS). Springfield, VA: National Technical Information Service.

Virtanen, S.M., Gasanen, L., Paganus, A., Pertti, V. and Akerblom, H.K. 1988. Intake of sugars and artificial sweeteners by adolescent diabetics. Nutr Reports Intl 38:1211-1218.

[redacted] **APPENDIX A** [redacted]

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APPENDIX A

IMPACT OF CHEWING GUM ON ERYTHRITOL CONSUMPTION ESTIMATES

Appendix A-1

Impact of Chewing Gum on Original Erythritol Consumption Estimates

Projection of Erythritol Intake by the Dietary Survey Approach

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We reviewed a report from Technical Assessment Systems, Inc. (TAS) regarding calculation of erythritol intake. The TAS report presents erythritol intakes for two groups of uses. The first group is for the combined intake from all uses expect for chewing gum. These calculations are done by the dietary survey approach for individuals reporting food intake in the U.S. Department of Agriculture Continuing Survey of Food Intakes by Individuals (CSFII) for the years 1989-92. The CSFII captured very few reports of chewing gum usage, and TAS concluded that the reported usage was unrepresentative. To cover chewing gum use, TAS used a market research survey from Market Facts to estimate chewing gum usage.

Because the CSFII-derived erythritol intakes and the Market Facts chewing gum use survey were performed on different survey populations, TAS did not merge these data. From research on the dietary survey approach, it is known that addition of a series of individual eaters-only additive intakes, reported for each food category, results in a unrepresentative overestimation of additive intake. Since the TAS eaters-only intake for the CSFII-generated food categories give a summary intake that accounts for this source of estimation, whereas the chewing gum survey does

not, it was decided to "normalize" the eaters-only intakes from these two surveys to create a projected eaters-only approach that would not include the source of overestimation.

To do this normalization, the erythritol eaters-only intakes for each of the specific food categories, for both the CSFII food categories and the chewing gum survey, were added and the sum was used as a denominator to derive a theoretical percent contribution that each of the food categories would theoretically contribute to the correct eaters-only intake. Through this process, it may be concluded that the chewing gum contribution to erythritol intake is theoretically 13% of the total for all individual food categories. This normalization factor is applied to the CSFII-generated summary eaters-only intakes by means of multiplication by factors of approximately 1.13. The individual calculations for the normalized eaters-only intakes for the all ages group for average and 90th percentile are shown in the attached.

The normalized eaters-only intakes for all proposed uses are: an average of 6.9 grams per day and a 90th percentile of 16.85 grams per day.

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Normalization of Erythritol intakes from

(1) the CFSII 7-food group combined and

(2) Market Facts chewing gum

I. Eaters-only (EO) average, all-age group.

From TAS table 1A, sum of separate EO average erythritol intakes for 7 food groups is 27.9637 grams per day (g/d). Market Facts (MF) chewing gum-erythritol intake is 4.13 g/d. The sum of 8-food group EO intakes is 32.0937. (Chewing gum is 12.9% of this sum.)

The normalized 8-food group EO intake is

$$\frac{32.0937}{27.9637} \times (6.0202) = 6.909 \text{ g/d}$$

II. Eaters-only 90th percentile, all-age group.

From TAS table 1A, sum of separate EO 90th percentile erythritol intakes for 7 food groups is 50.1848 g/d. MF chewing gum-erythritol intake is 8.10 g/d. The sum of 8-food group EO intakes is 58.2848. (Chewing gum is 13.9% of this sum).

The normalized 8-food group EO intake is

$$\frac{58.2848}{50.1848} \times 14.5136 = 16.8546 \text{ g/d.}$$

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Appendix A-2

Impact of Chewing Gum on Expanded Erythritol Consumption Estimates

Normalization of Erythritol Intakes From The USDA CSFII Food Consumption Database And The Market Facts Chewing Gum Survey

I. Users-only average, total population group.

Sum of separate average erythritol intakes for 11 food groups (see Appendix C, Table C-5) is 74.44 grams per day (g/d). Market Facts erythritol intake from chewing gum is 4.13 g/day. The sum of 12-food group intakes is 78.57 g/d (Chewing gum is 5.25 % of this sum).

The normalized 12 -food group erythritol intake is

$$\frac{(78.57)}{74.54} \times (13.40)\ g = 14.13\ g/day$$

II. Users-only 90th percentile, total population group.

Sum of separate average erythritol intakes for 11 food groups (See Appendix C, Table C-5) is 147.49 grams per day (g/d). Market Facts erythritol intake from chewing gum is 8.10 g/day. The sum of 12-food group intakes is 155.59 g/d (Chewing gum is 5.21 % of this sum).

The normalized 12-food group erythritol intake is

$$\frac{(155.59)}{147.49} \times (29.2)\ g = 30.80\ g/day$$

APPENDIX B

APPENDIX B

SUMMARY OF CURRENT USES AND USE LEVELS OF POLYOLS MARKETED IN THE UNITED STATES

Sugar Alcohols - FDA Regulatory Status

Sugar Alcohol	FDA Regulatory Status	Functionality	Intended Uses	Caloric Value (calories/gm)	Laxation Warning
Hydrogenated Starch Hydrolysate (5-10% maltitol, ≤ 15% sorbitol, 7-12% hydrogenated trisaccharides, and 63-69% hydrogenated oligosaccharides greater than tri -)	Self-determined GRAS substance - Lonza, Inc.'s GRAS petition (5G0304) filed 2/24/86.	*flavoring agent/adjuvant *formulation aid *humectant *nutritive sweetener *processing aid *sequestrant *stabilizer/thickener *surface-finishing agent *texturizer	98.9% in hard candy 89.8 % in taffy 77% in caramel 74.8% in chocolate chewy confection 21.3% in granola bars	3.0	Not proposed in GRAS petition
Isomalt	Self-determined GRAS substance - Suddeutsche Zucker AG/Bayer AG's GRAS petition (6G0321) filed 10/19/90.	*flavor enhancer *flavoring agent/adjuvant *formulation aid *nutritive sweetener *sequestrant *stabilizer/thickener *surface-finishing agent *synergist *texturizer	40% in baked goods 20% in breakfast cereals 80% in chewing gum 45% in confections/frostings 15% in frozen dairy dessert/fruit ices 55% in gelatins, puddings & fillings 99% in hard candies/cough drops 25% in jams/jellies 20% in milk (non-beverage) products and snack foods 45% in soft candies 100% in sugar substitutes	2.0	Per GRAS petition, when reasonably forseeable consumption of a food may result in 50 gm daily intake
Lactitol	Self-determined GRAS substance - Purac Biochem, B.V.'s GRAS petition (2G0391) filed 9/10/93.	*formulation aid *nutritive sweetener *stabilizer/thickener *texturizer	99% in hard candy/cough drops 75% in chewing gum 65% in soft candy 14% in frozen dairy desserts & mixes	2.0	Per GRAS petition, when reasonably forseeable consumption of a food may result in 50 gm daily intake
Maltitol Powder (≥ 88.5% maltitol, ≤ 3% sorbitol, ≤ 9% hydrogenated trisaccharides and ≤ 3% hydrogenated oligosaccharides greater than tri-)	Self-determined GRAS substance - TOWA Chemical Industry Co., Ltd's GRAS petition (6G0319) filed 12/23/86.	*flavoring agent/adjuvant *formulation aid *humectant *nutritive sweetener *processing aid *sequestrant *stabilizer/thickener *surface-finishing agent *texturizer	99.5% in hard candy/cough drops 99% in sugar substitutes 85% in soft candy 75% in chewing gum 55% in non-standardized jams & jellies 30% in cookies & sponge cake	3.0	Per GRAS petition, when reasonably forseeable consumption of a food may result in 100 gm daily intake

Sugar Alcohols - FDA Regulatory Status

Sugar Alcohol	FDA Regulatory Status	Functionality	Intended Uses	Caloric Value (calories/gm)	Laxation Warning
Maltitol Syrup (hydrogenated glucose syrup) (50-55% maltitols, ≤ 8% sorbitol, 19-27.3% hydrogenated tri- to hexasaccharides and 13-20.5% hydrogenated saccharides greater than hexa-)	Self-determined GRAS substance - Roquette Corp.'s GRAS petition (3G0286) filed 2/27/84.	*flavoring agent/adjuvant *formulation aid *humectant *nutritive sweetener *processing aid *sequestrant *stabilizer/thickener *surface-finishing agent *texturizer	99.5% in hard candy/cough drops 85% in soft candy 80% in confections/frostings 30% in chewing gum	3.0	Per GRAS petition, when reasonably forseeable consumption of a food may result in 100 gm daily intake
Mannitol	Food additive permitted on an interim basis pending additional study, 21 CFR 180.25	*anticaking/free-flow agent *formulation aid *firming agent *flavoring agent/adjuvant *lubricant/release agent *nutritive sweetener *processing aid *surface-finishing agent *texturizer	98% in pressed mints 5% in other hard candy/cough drops 31% in chewing gum 40% in soft candy 80% in confections/frostings 15% non-standardized jams & jellies <2.5% in all other foods	1.6	Per 21 CFR 180.25(e), when reasonably forseeable consumption of a food may result in 20 gm daily intake
Sorbitol	FDA-affirmed GRAS substance, 21 CFR 184.1835 USDA-approved substance, 9 CFR 318.7(c)(4).	*anticaking agent *curing/pickling agent *drying agent *emulsifier *firming agent *flavoring agent *formulation aid *humectant *lubricant *nutritive sweetener *sequestrant *stabilizer/thickener *surface-finishing agent *texturizer	99% in hard candy/cough drops 75% in chewing gum 98% in soft candy 30% non-standardized jams & jellies 30% in baked goods & baking mixes 17% in frozen dairy desserts & mixes 2% in processed meat products 12% in all other foods	2.6	Per 21 CFR 184.1835(e), when reasonably forseeable consumption of a food may result in 50 gm daily intake

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APPENDIX C

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Appendix C-2

Summary Tables of Erythritol Uses and USDA CSFII Food Codes

Projected USDA CSFII Expanded Food-Use Categories/Codes for Erythritol

Bakery Fillings (fruit, cream, custard, pudding fillings)

Fruit fillings
[erythritol] = 15%

1321081	P.R. Pumpkin Pudding (Flan De Calabaza)
6111350	Lemon Pie Filling
6311303	Cherry Pie Filling
6311305	Cherry Pie Filling, Low Calorie
6320370	Blueberry Pie Filling

Cakes containing fruit, cream and custard, or pudding fillings (24% filling)(15% erythritol)
[erythritol] = 3.6%

5310280	Cake, Black Forest (Choc-cherry)
5310350	Cake, Butter, Not Specified as to Icing
5310355	Cake, Butter, Without Icing
5310360	Cake, Butter, with Icing
5310495	Cake, Choc, Made with Mayonnaise, with Icing or Filling
5310530	Cake, German Choc, with Icing and Filling
5310565	Cake, Chocolate, Devil's Food/Fudge, Pudding Type, No Cholesterol, Not Specified as to Icing
5310570	Cake, Chocolate, Devil Food's/Fudge, Pudding Type, No Cholesterol, No Icing
5310575	Cake, Chocolate, Devil Food's/Fudge, Pudding Type, No Chocolate, Lite Icing
5310590	Cake, Chocolate, Devil's Food/Fudge, Pudding Mix, Not Specified Icing
5310600	Cake, Chocolate, Devil's Food/Fudge, Pudding Mix, Without Icing
5310605	Cake, Chocolate, Devil's Food/fudge, Pudding Mix, With Icing
5310820	Cake, Cupcake, Chocolate, with Icing or Filling
5310920	Cake, Cupcake, Not Chocolate, with Icing or Filling
5310925	Cupcake, Not Chocolate, with Fruit and Cream Filling
5310930	Cake, dobos Torte (Non-Chocolate Cake with Chocolate Fill and Icing
5311300	Cake, Jelly Roll
5311400	Cake, Lemon, Without Icing
5311420	Cake, Lemon, Low Fat, Without Icing
5311530	Cake, Nut, Not Specified as to Icing
5311531	Cake, Nut, Without Icing
5312030	Cake, White, Pudding-type Mix, Not Specified as to Icing
5312033	Cake, White, Pudding-type Mix, Without Icing
5312035	Cake, White, Pudding-type Mix, with Icing
5312128	Cake, Yellow, Pudding Mix, Not Specified as to Icing
5312130	Cake, Yellow, Pudding Mix, Without Icing

5312133	Cake, Yellow, Pudding Mix, with Icing
5361025	Coffee Cake, Quick-bread Type, Custard Filled

Cookies containing fruit, cream and custard, or pudding fillings (18.8% filling)(15% erythritol) [erythritol] = 2.8%

5322000	Cookie, Fruit-filled
5320100	Cookie, Not Specified as to Type
5320605	Cookie, Rich, Chocolate Chip, with Chocolate Filling
5320610	Cookie, Chocolate Chip Sandwich
5320900	Cookie, Chocolate, Chocolate Sandwich/chocolate-coated/striped
5320901	Cookie, Chocolate-cover, Sugar Wafer, Creme/caramel Filled
5320905	Cookie, Chocolate Sandwich, Chocolate Covered
5320910	Cookie, Chocolate, Sandwich, with Extra Filling
5320950	Cookie, Chocolate and Vanilla Sandwich
5322000	Cookie, Fruit-filled
5322002	Cookie, Date Bar
5322003	Cookie, Fig Bar
5323302	Cookie, Oatmeal, with Fruit Filling
5323305	Cookie, Oatmeal Sandwich, with Creme Filling
5323701	Cookie, Raisin Sandwich, Cream-filled
5323800	Cookie, Sandwich Type, Not Chocolate or Vanilla
5323905	Cookie, Shortbread, with Chocolate Filling
5324200	Cookie, Sugar Wafer
5324300	Cookie, Vanilla Sandwich
5324310	Cookie, Rich, Chocolate, with Chocolate Filling
5324401	Cookie, Butter/sugar, with Chocolate Icing / Filling
5324500	Cookie, Vanilla Waffle Creme
5326010	Cookie, Dietetic, Fruit Types
5326030	Cookie, Dietetic, Sandwich Type

Pastries containing fruits, cream and custard, or pudding fillings (32.5% filling)(15% erythritol) [erythritol] = 4.9%

5340030	Blintz, Fruit-filled
5341010	Cobbler, Apple (Includes Fruit Cobbler)
5341020	Cobbler, Apricot
5341030	Cobbler, Berry
5341050	Cobbler, Cherry
5341080	Cobbler, Peach
5341085	Cobbler, Pear
5341086	Cobbler, Pineapple
5341088	Cobbler, Plum

5341090	Cobbler, Rhubarb
5341510	Crisp, Apple, Apple Dessert
5341512	Fritter, Apple
5341520	Fritter, Banana
5341522	Fritter, Berry
5341530	Crisp, Blueberry
5341540	Crisp, Cherry
5341550	Crisp, Peach
5341560	Crisp, Rhubarb
5342000	Cream Puff/eclair, Custard/cream-filled, Not Specified Icing
5342010	Cream Puff/eclair, Custard/cream-filled, Not Iced
5342020	Cream Puff/eclair, Custard/cream-filled, Iced
5343000	Crepe, Dessert Type, Not Specified as to Filling
5343010	Crepe, Dessert Type, Chocolate-filled
5343020	Crepe, Dessert Type, Fruit-filled
5344000	Strudel, Apple (Includes Strudel, NFS)
5344030	Strudel, Berry
5344050	Strudel, Cherry
5344060	Strudel, Cheese
5344070	Strudel, Peach
5344075	Strudel, Pineapple
5344080	Strudel, Cheese and Fruit
5345000	Turnover or Dumpling, Apple
5345030	Turnover or Dumpling, Berry
5345050	Turnover or Dumpling, Cherry
5345080	Turnover or Dumpling, Lemon
5345100	Turnover or Dumpling, Peach
5345150	Turnover, Guava
5345175	Turnover, Pumpkin
5345210	Pastry, Fruit-filled
5345242	Pastry, Puff, Custard/cream Filled, Iced/not Iced
5345315	Empanada, Fruit-filled
5345317	Empanada, Pumpkin
5352114	Doughnut, Jelly
5352121	Doughnut, Custard-filled
5352122	Doughnut, Chocolate Cream-filled
5352123	Doughnut, Custard-filled, with Icing
5353000	Breakfast Tart
5354020	Breakfast Bar, Cereal Crust, with Fruit Filling
5361025	Coffee Cake, Quick-bread Type, Custard Filled
5410220	Cracker, Graham, Sandwich-type, Vanilla Filling

Pies containing fruit, cream and custard, or pudding fillings (57% filling)(15% erythritol) [erythritol] = 8.6%

5330010	Pie, NFS
5330017	Pie, Individual Size or Tart, NFS
5330018	Pie, Fried, NFS
5330100	Pie, Apple, Two Crust
5330108	Pie, Apple, Fried (Includes McDonald's)
5330400	Pie, Blueberry, Two Crust
5330405	Pie, Blueberry, One Crust
5330500	Pie, Cherry, Two Crust
5330501	Pie, Cherry, One Crust
5330507	Pie, Cherry, Individual Size or Tart
5330508	Pie, Cherry, Fried (Includes McDonald's)
5330570	Pie, Lemon (Not Cream or Meringue)
5330572	Pie, Lemon (Not Cream or Meringue), Individual Size
5330575	Pie, Lemon, Fried
5330700	Pie, Peach, Two Crust
5330705	Pie, Peach, One-crust
5330707	Pie, Peach, Individual Size or Tart
5330708	Pie, Peach, Fried
5330750	Pie, Pear, Two Crust
5330757	Pie, Pear, Individual Size or Tart
5330800	Pie, Pineapple, Two Crust
5330807	Pie, Pineapple, Individual Size or Tart
5330830	Pie, Plum, Two Crust
5330850	Pie, Prune, One Crust
5330900	Pie, Raisin, Two Crust
5330907	Pie, Raisin, Individual Size or Tart
5331000	Pie, Raspberry, One Crust
5331005	Pie, Raspberry, Two Crust
5331100	Pie, Rhubarb, Two Crust
5331105	Pie, Rhubarb, One Crust
5331107	Pie, Rhubarb, Individual Size or Tart
5331200	Pie, Strawberry, One Crust
5331300	Pie, Strawberry-rhubarb, Two Crust
5331400	Pie, Strawberry, Individual Size or Tart
5334000	Pie, Apple-sour Cream
5334050	Pie, Cherry, with Cream Cheese and Sour Cream
5334100	Pie, Banana Cream
5334107	Pie, Banana Cream, Individual Size or Tart
5334200	Pie, Chocolate Cream
5334207	Pie, Chocolate Cream, Individual Size or Tart

5334300	Pie, Coconut Cream
5334307	Pie, Coconut Cream, Individual Size or Tart
5334400	Pie, Custard
5334407	Pie, Custard, Individual Size or Tart
5334500	Pie, Lemon Cream
5334507	Pie, Lemon Cream, Individual Size or Tart
5334600	Pie, Peanut Butter Cream
5334650	Pie, Pineapple Cream
5334700	Pie, Pumpkin
5334707	Pie, Pumpkin, Individual Size or Tart
5334710	Pie, Raspberry Cream
5334750	Pie, Sour Cream, Raisin
5334800	Pie, Strawberry Cream
5334807	Pie, Strawberry Cream, Individual Size or Tart
5336500	Pie, Vanilla Cream
5338100	Pie, Lemon Meringue
5338107	Pie, Lemon Meringue, Individual Size or Tart
5338600	Pie, Pudding, Not Chocolate
5338605	Pie, Pudding, Not Choc, Individual Size
5338625	Pie, Pudding, Choc, with ChocolateCoating, Individual Size
5338650	Pie, Pudding, Not Choc, Choc-coated, Individual Size

Pudding (including instant (phosphate set) puddings)
[erythritol] = 10%

1320011	Pudding, NFS
1321022	Pudding, Chocolate, Not Specified as From Dry Mix or Canned
1321025	Pudding, Chocolate, Low Calorie, with Artificial Sweetener (D-zerta, jello)
1321028	Pudding, Not Chocolate, Not Specified as From Dry Mix or Canned
1321029	Pudding, Not Chocolate, Low Calorie, with Artificial Sweetener (D-zerta)
1321053	Pudding, Tapioca Chocolate, with Milk, Not Specified as to type of Milk
1321061	Pudding, Coconut
1321075	Pudding, Pumpkin
1322011	Pudding, from Dry Mix, Milk Added, Not Specified as to type of Milk, not Chocolate
1322012	Pudding, from Dry Mix, Milk Added, Not Specified as to type of Milk, Chocolate
1322021	Pudding, Prepared with Dry Mix, Low Calorie, with Artificial Sweetener, Milk Added
1322022	Pudding, Prepared with Dry Mix, Low Calorie, with Artificial Sweetener, Milk
1322023	Pudding, Chocolate, Reduced Fat (Includes Jell-o Light)
1322024	Pudding, Not Choc, Reduced Fat (Includes Jell-o Light)
1323011	Pudding, Canned, Not Chocolate
1323012	Pudding, Canned, Low Calorie, with Artificial Sweetener, not Chocolate

1323013	Pudding, Canned, Chocolate
1323014	Pudding, Canned, Low Calorie, with Artificial Sweetener, Chocolate
1323020	Pudding, Commercial Preparation, Choc and Non-Chocolate Flavors Combined
1323500	Pudding, Pops, Chocolate
1323510	Pudding, Pops, Not Chocolate
1323600	Pudding Roll-up, Chocolate
1323610	Pudding Roll-up, Not Chocolate
1324011	Pudding, Sodium Controlled, Milk Base
1324100	Pudding, with Fruit and Vanilla Wafers

Pudding mixtures (54.5% pudding)(10% erythritol)
[erythritol] = 5.45%

6340299	Fruit Salad (With Citrus) with Pudding
6340300	Fruit Salad (No Citrus Fruits) with Pudding
6340310	Fruit Dessert with Cream and/or Pudding and Nuts

Cakes and Cookies
(includes deposited, rotary molded and wire cut cookies, batter type and foam type cakes)

Cakes without icing or fillings
[erythritol] = 15%

5310005	Cake, Batter, Chocolate, Raw
5310007	Cake, Batter, Raw, Not Chocolate
5310010	Cake, Not Specified as to Type, with or Without Icing
5310100	Cake, Angel Food, Not Specified as to Icing
5310110	Cake, Angel Food, Without Icing
5310130	Cake, Angel Food, Choc, Without Icing
5310200	Cake, Applesauce, Not Specified as to Icing
5310210	Cake, Applesauce Without Icing
5310230	Cake, Applesauce, Diet, Without Icing
5310250	Cake, Banana, Not Specified as to Icing
5310260	Cake, Banana, Without Icing
5310350	Cake, Butter, Not Specified as to Icing
5310355	Cake, Butter, Without Icing
5310400	Cake, Carrot, Not Specified as to Icing
5310410	Cake, Carrot, No Icing
5310430	Carrot Cake, Diet
5310450	Cheesecake
5310455	Cheesecake, with Fruit
5310460	Cheesecake, Chocolate
5310490	Cake, Choc, Made with Mayonnaise, Not Specified as to Icing

5310492	Cake, Choc, Made with Mayonnaise, Without Icing
5310500	Cake, Chocolate, Devil's Food/Fudge, Standard Mix, Not Specified as to Icing
5310510	Cake, Chocolate, Devil's Food/Fudge, Standard Mix, Without Icing
5310565	Cake, Chocolate, Devil's Food/Fudge, Pudding Type, No Cholesterol, Not Specified as to Icing
5310570	Cake, Chocolate, Devil Food's/Fudge, Pudding Type, No Cholesterol, No Icing
5310590	Cake, Chocolate, Devil's Food/Fudge, Pudding Mix, Not Specified Icing
5310600	Cake, Chocolate, Devil's Food/Fudge, Pudding Mix, Without Icing
5310610	Cake, Poor Man's (Spice-type), Without Icing
5310650	Cake, Cream, Without Icing or Topping
5310700	Cake, Cupcake, Not Specified as to Type and Icing
5310710	Cake, Cupcake, Not Specified as to Type, Without Icing
5310800	Cake, Cupcake, Chocolate, Not Specified as to Icing
5310810	Cake, Cupcake, Chocolate, Without Icing
5310900	Cake, Cupcake, Not Chocolate, Not Specified as to Icing
5310910	Cake, Cupcake, Not Chocolate, Without Icing or Filling
5311000	Cake, Fruitcake, Light/dark
5311100	Cake, Gingerbread, Without Icing
5311150	Cake, Graham Cracker, Without Icing
5311395	Cake, Lemon, Not Specified as to Icing
5311400	Cake, Lemon, Without Icing
5311415	Cake, Lemon, Low Fat, Not Specified as to Icing
5311420	Cake, Lemon, Low Fat, Without Icing
5311500	Cake, Marble, Not Specified as to Icing
5311510	Cake, Marble, Without Icing
5311530	Cake, Nut, Not Specified as to Icing
5311531	Cake, Nut, Without Icing
5311540	Cake, Oatmeal, Without Icing
5311560	Cake, Poppyseed, Without Icing
5311600	Cake, Pound, Without Icing
5311627	Cake, Pound, Chocolate
5311628	Cake, Pound, Choc, Very Lofat, No Cholesterol (Includes Entenmanns)
5311635	Cake, Pound, P.R. (Ponque)
5311638	Cake, Pound, Very Low Fat, No Cholesterol (Includes Entenmanns)
5311649	Cake, Pumpkin, Not Specified Icing
5311650	Cake, Pumpkin, Without Icing
5311655	Cake, Raisin-nut, Without Icing
5311700	Cake, Spice, Not Specified as to Icing
5311710	Cake, Spice, Without Icing
5311800	Cake, Sponge, Not Specified as to Icing
5311810	Cake, Sponge, Without Icing
5311830	Cake, Sponge, Chocolate, Without Icing
5311841	Cake, Rum Flavored Without Icing

5312000	Cake, White, Standard Mix, Not Specified as to Icing
5312010	Cake, White, Standard Mix, Without Icing
5312030	Cake, White, Pudding-type Mix, Not Specified as to Icing
5312033	Cake, White, Pudding-type Mix, Without Icing
5312040	Cake, White, Eggless, Lowfat
5312050	Cake, Whole Wheat, with Fruit and Nuts, Without Icing
5312100	Cake, Yellow, Standard Mix, Not Specified as to Icing
5312110	Cake, Yellow, Standard Mix, Without Icing
5312128	Cake, Yellow, Pudding Mix, Not Specified as to Icing
5312130	Cake, Yellow, Pudding Mix, Without Icing
5312410	Cake, Zucchini, Not Specified as to Icing
5312411	Cake, Zucchini, Without Icing

Cakes with icing and filling (adjustment for cake = 73%)(erythritol =15%)
[erythritol] = 11.0%

5310120	Cake, Angel Food, with Icing
5310220	Cake, Applesauce with Icing
5310270	Cake, Banana, with Icing
5310280	Cake, Black Forest (Choc-cherry)
5310300	Cake, Boston Cream Pie
5310360	Cake, Butter, with Icing
5310426	Cake, Carrot, with Icing
5310430	Carrot Cake, Diet
5310495	Cake, Choc, Made with Mayonnaise, with Icing or Filling
5310520	Cake, Chocolate, Devil's Food/Fudge, Standard Mix, with Icing
5310530	Cake, German Choc, with Icing and Filling
5310550	Cake, Choc, with Icing, Diet
5310560	Cake, Chocolate/Devil's Food, Pudding Mix, Lite Recipe, with Icing
5310575	Cake, Chocolate, Devil Food's/Fudge, Pudding Type, No Chocolate, Lite Icing
5310605	Cake, Chocolate, Devil's Food/fudge, Pudding Mix, With Icing
5310720	Cake, Cupcake, Not Specified as to Type, With Icing
5310820	Cake, Cupcake, Chocolate, with Icing or Filling
5310920	Cake, Cupcake, Not Chocolate, with Icing or Filling
5310921	Cake, Cupcake, Not Chocolate, with Icing, Reduced Fat, No Cholesterol
5310925	Cupcake, Not Chocolate, with Fruit and Cream Filling
5310927	Cupcake, Chocolate, with or without Icing, Fruit/cream Fill, Low Fat
5310930	Cake, dobos Torte (Non-Chocolate Cake with Chocolate Fill and Icing)
5311250	Cake, Ice Box, with Fruit and Whipped Cream
5311300	Cake, Jelly Roll
5311410	Cake, Lemon, with Icing
5311425	Cake, Lemon, Low Fat, with Icing
5311520	Cake, Marble, with Icing

5311532	Cake, Nut, with Icing
5311541	Cake, Oatmeal, With Icing
5311545	Cake, Peanut Butter, with Icing
5311550	Cake, Pineapple, Very Low Fat, with Icing
5311602	Cake, Pound, with Icing
5311651	Cake, Pumpkin, with Icing
5311656	Cake, Raisin-nut, with Icing
5311720	Cake, Spice, with Icing
5311820	Cake, Sponge, with Icing
5311831	Cake, Sponge, Chocolate, with Icing
5311835	Cake, Sweet Potato, with Icing (Includes with Glaze)
5311850	Cake, Torte
5311860	Cake, Chiffon, Not Specified as to Icing
5311870	Cake, Chiffon, Without Icing
5311880	Cake, Chiffon, with Icing
5311890	Cake, Chiffon, Chocolate, Without Icing
5311895	Cake, Chiffon, Chocolate, with Icing
5311900	Cake, Upside Down (All Fruits)
5312020	Cake, White, Standard Mix, with Icing
5312035	Cake, White, Pudding-type Mix, with Icing
5312120	Cake, Yellow, Standard Mix, with Icing
5312133	Cake, Yellow, Pudding Mix, with Icing
5312412	Cake, Zucchini, with Icing

Mixtures containing cake (adjustment for cake = 54%) (erythritol = 15%) [erythritol] = 8.1%

1312030	Ice Cream Bar, Cake-covered
1312150	Ice Cream Sundae, Fudge Topping, with Cake
1317000	Baked Alaska
1321016	Diplomat Pudding, P.R. (Budin Diplomatico)
5311200	Cake, Ice Cream and Cake Roll, Chocolate
5311210	Cake, Ice Cream and Cake Roll, Not Chocolate
5311215	Cake, Frozen Yogurt and Cake Layer, Not Chocolate, with Icing
5311216	Cake, Frozen Yogurt and Cake Layer, Chocolate, with Icing
5312208	Cake, Shortcake, Biscuit, with Fruit
5312307	Cake, Shortcake, Sponge, with Whipped Cream and Fruit
5312307	Cake, Shortcake, Sponge, with Whipped Cream and Fruit
5312308	Cake, Shortcake, Sponge, with Fruit
5312350	Cake, Shortcake, with Whip Topping and Fruit, Diet

Cookies without icing or fillings
[erythritol] = 15%

5320010	Cookie, Batter, Raw, Not Chocolate
5320100	Cookie, Not Specified as to Type
5320200	Cookie, Almond
5320310	Cookie, Baby (Includes Gerber Animal Shaped Cookies)
5320400	Cookie, Brownie, Not Specified as to Icing
5320401	Cookie, Brownie, Without Icing
5320480	Brownie, Diet, Not Specified as to Icing
5320500	Cookie, Butter
5320525	Cookie, Butterscotch, Brownie
5320550	Cookie, Butterscotch Chip
5320575	Cookie, Carob
5320576	Cookie, Carob and Honey Brownie
5320600	Cookie, Chocolate Chip
5320601	Cookie, Chocolate Chip with Raisins
5320602	Cookie, ChocolateChip, Homemade or Purchased At Bakery
5320650	Cookie, Chocolate, Made with Rice Cereal (No-bake)
5320655	Cookie, Chocolate, Made with Oatmeal and Coconut
5321100	Cookie, Bar, with Chocolate, Nuts, and Graham Crackers
5321500	Cookie, Coconut Bars
5321550	Cookie, Coconut
5321600	Cookie, Coconut and Nut
5322201	Cookie, Fortune
5322202	Cookie, Cone Shell, Ice Cream Type, Wafer / Cake
5322210	Cookie, Cone Shell, Ice Cream Type, Brown Sugar
5322212	Cookie, Cone Shell, Ice Cream Type, Waffle
5322300	Cookie, Gingersnaps
5322310	Cookie, Granola
5322400	Cookie, Lady Finger
5322500	Cookie, Macaroon
5323000	Cookie, Molasses
5323100	Cookie, Lebkuchen
5323140	Cookie, Multigrain, High Fibre
5323300	Cookie, Oatmeal
5323301	Cookie, Oatmeal, with Raisins or Dates
5323306	Cookie, Oatmeal, with Chocolate Chips
5323310	Cookie, Oatmeal, with Chocolateand Peanut Butter (No-bake)
5323350	Cookie, Oat Bran
5323400	Cookie, Peanut Butter (Includes Pb Wafer)
5323401	Cookie, Peanut Butter with Oatmeal
5323410	Cookie, Peanut Butter, with Chocolate (Includes Nassau)

5323425	Cookie, Peanut Butter with Rice Cereal (No-bake)
5323500	Cookie, Peanut
5323560	Cookie, Pfeffernusse
5323600	Cookie, Pizzelle (Italian Style Wafer)
5323610	Cookie, Pumpkin
5323700	Cookie, Raisin
5323750	Cookie, Rum Ball (No-bake)
5323900	Cookie, Shortbread
5324100	Cookie, Sugar
5324150	Cookie, Butter or Sugar
5324160	Cookie, Butter/sugar Cookie, with Fruit And/ or Nuts
5324225	Cookie, Teething
5324250	Cookie, Toffee Bar
5324600	Cookie, Tea, Japanese
5324800	Cookie, Whole Wheat, Dried Fruit and Nuts
5325110	Cookie, Rugelach
5326000	Cookie, Dietetic, NFS
5326003	Cookie, Dietetic, Chocolate Chip
5326005	Cookie, Dietetic, Chocolate Flavored
5326020	Cookie, Dietetic, Oatmeal with Raisins
5326040	Cookie, Dietetic, Sugar or Plain
5327010	Cookie, P.R. (Mantecaditos Polvorones)

Cookies with icing or fillings (cookie adjustment = 72%) (erythritol = 15%) [erythritol] = 10.8%

5320300	Cookie, Applesauce
5320410	Cookie, Brownie, with Icing
5320450	Cookie, Brownie, with Cream Cheese Filling, Without Icing
5320460	Cookie, Brownie, with Peanut Butter Fudge Icing
5320560	Cookie, Caramel Coated, with Nuts
5320605	Cookie, Rich, Chocolate Chip, with Chocolate Filling
5320610	Cookie, Chocolate Chip Sandwich
5320700	Cookie, Chocolate Fudge
5320800	Cookie, Chocolate-covered, Marshmallow
5320820	Cookie, Chocolate-covered, Marshmallow Pie
5320900	Cookie, Chocolate, Chocolate Sandwich/chocolate-coated/striped
5320901	Cookie, Chocolate-cover, Sugar Wafer, Creme/caramel Filled
5320905	Cookie, Chocolate Sandwich, Chocolate Covered
5320910	Cookie, Chocolate, Sandwich, with Extra Filling
5320950	Cookie, Chocolate and Vanilla Sandwich
5321000	Cookie, Chocolate Wafer
5321090	Cookie, Graham Cracker Sandwich with Chocolate and Marshmellow

5322000	Cookie, Fruit-filled
5322002	Cookie, Date Bar
5322003	Cookie, Fig Bar
5322425	Cookie, Lemon Bar
5322600	Cookie, Marshmallow, with Coconut
5322650	Cookie, Marshmallow, with Rice Cereal (No-bake)
5322700	Cookie, Marshmallow Pie, Nonchocolate Coating
5323302	Cookie, Oatmeal, with Fruit Filling
5323305	Cookie, Oatmeal Sandwich, with Creme Filling
5323550	Cookie, with Peanut Butter Filling, Chocolate-coated
5323701	Cookie, Raisin Sandwich, Cream-filled
5323800	Cookie, Sandwich Type, Not Chocolate or Vanilla
5323905	Cookie, Shortbread, with Chocolate Filling
5324200	Cookie, Sugar Wafer
5324300	Cookie, Vanilla Sandwich
5324310	Cookie, Rich, Chocolate, with Chocolate Filling
5324401	Cookie, Butter/sugar, with Chocolate Icing / Filling
5324402	Cookie, Butter/sugar, Iced, with Icing Not Choc
5324500	Cookie, Vanilla Waffle Creme
5324700	Cookie, Vanilla Wafer, Not Specified as to Type
5324750	Cookie, Vanilla with Caramel, Coconut, ChocolateCoating
5326001	Cookie, Dietetic, Apple Pastry
5326010	Cookie, Dietetic, Fruit Types
5326015	Cookie, Lemon Wafer, Low Fat
5326030	Cookie, Dietetic, Sandwich Type

Mixtures containing cookie (6.3% adjustment for cookie)(erythritol = 15%)
[erythritol] = 1.0%

1312070	Ice Cream Cone, with Nuts, Not Chocolate
1312071	Ice Cream Cone, Chocolate-covered, with Nuts, Not Choc
1312072	Ice Cream Cone, Chocolate-covered or Dipped, Not Choc
1312073	Ice Cream Cone, No Topping, Not Chocolate
1312074	Ice Cream Cone, No Topping, Not Specified as to Flavor
1312075	Ice Cream Cone, Withnuts, Chocolate Ice Cream
1312076	Ice Cream Cone, Chocolate-covered, Chocolate Ice Cream
1312077	Ice Cream Cone, No Topping, Chocolate Ice Cream
1312078	Ice Cream Cone, Chocolate-covered, Withnut, Chocolate Ice Cream
1312079	Ice Cream Sundae Cone (Includes Drumstick, All Flavors)
1313062	Ice Milk, Soft Serve Cone,not Chocolate(Includes Dairy Queen
1313063	Ice Milk, Soft Serve Cone, Chocolate
1314045	Ice Milk Cone, NFS

1314050	Ice Milk Cone, Not Chocolate
1314055	Ice Milk Cone, Chocolate

Canned/Bottled Low Calorie/Sugar Free Carbonated and Noncarbonated Soft Drinks (includes canned/bottled low calorie/sugar free carbonated soft drinks and canned/bottled/dry mix low calorie/sugar free noncarbonated beverages)

Carbonated soft drinks (Low-calorie, unsweetened, sugar free)
[erythritol] = 3.5%

9240010	Soft Drink, NFS, Sugar-free
9241021	Carbonated Water, Unsweetened (Includes Club Soda)
9241025	Tonic Water, Sugar-free
9241032	Soft Drink, Cola-type, Sugar-free
9241035	Soft Drink, Cola-type, Decaffeinated, Sugar-free
9241037	Soft Drink, Pepper-type, Sugar-free
9241040	Soft Drink, Pepper-type, Decaffeinated, Sugar-free
9241042	Cream Soda, Sugar-free
9241052	Soft Drink, Fruit-flav, Sugar-free, Caffeine Free
9241056	Soft Drink, Fruit-flavored, with Caffeine, Sugar-free
9241062	Gingerale, Sugar-free
9241072	Root Beer, Sugar-free
9241082	Chocolate-flavored Soda, Sugar-free
9241161	Cola with Fruit or Vanilla Flavor, Sugar-free
9241162	Cola with ChocolateFlavor, Sugar Free
9242110	Soft Drink, Fruit-flavored, with 10% Fruit Juice, Low Calorie

Non-carbonated canned/bottled beverages (sugar free/low calorie)
[erythritol] = 3.5%

6411604	Grape Juice, Low Calorie Sweetener
9230108	Tea, Presweetened with Low Calorie Sweetener
9230330	Tea, Ready-to-drink, Low Calorie Sweetener
9230118	Tea, Decaffeinated, Low Calorie Sweetener, NFS
9252041	Fruit Drink, Low Calorie
9252081	Grape Drink, Low Calorie
9252091	Lemonade, Low Calorie
9255005	Apple-White Grape Juice Drink, Low Calorie, with Vitamin C Added
9255011	Cranberry Juice Cocktail, Low Calorie, with Vitamin C Added
9255021	Cranberry-Apple Juice Drink, Low Calorie, Vitamin C Added
9255030	Grapefruit Juice Drink, Low Calorie, with Vitamin C
9255061	Fruit-flavored Drink, Low Calorie, with Vitamin C Added
9255160	Citrus Juice Drink, Low Calorie

9255170	Juice Drink, Low Calorie
9255210	Orange-Cranberry Juice Drink, Low Calorie, with Vitamin C Added
9256000	Fruit-flavored Beverage, Low Sugar
9258200	Fruit-flavored Drink, Low Calorie, Calcium-fortified

Dairy Drinks
(includes imitation soy milks, chocolate milk, flavored milks, milk based smoothies)

Imitation dairy drinks (soy based)
[erythritol] = 3.5%

1131000	Milk, Imitation, Fluid, Soy Based
1132000	Milk, Soy, Fluid, Canned, Not Baby
1133000	Milk, Soy, Dry, Reconstituted, Not Baby
1134000	Milk, Imitation, Fluid, Corn-Syrup Base (Includes Vitamite)

Dairy drinks (chocolate milk/flavoured milks, milk based smoothies)
[erythritol] = 3.5%

1151100	Milk, Chocolate, NFS
1151110	Milk, Chocolate, Whole Milk Based
1151120	Milk, Chocolate, Lowfat Milk Based
1151130	Milk, Chocolate, Skim Milk Based
1151200	Cocoa, Hot Chocolate, not From Dry Mix, With Whole Milk
1151250	Hot Chocolate Drink with Evaporated Milk, Puerto Rican
1151300	Cocoa and Sugar Mixture, Milk Added, Not Specified Type Milk
1151310	Cocoa and Sugar Mixture, Whole Milk Added
1151320	Cocoa and Sugar Mixture, Lowfat Milk Added
1151330	Cocoa and Sugar Mixture, Skim Milk Added
1151340	Chocolate Syrup Milk Added, Not Specified as to Type of Milk
1151350	Chocolate Syrup, Whole Milk Added
1151360	Chocolate Syrup, Lowfat Milk Added
1151370	Chocolate Syrup, Skim Milk Added
1151410	Cocoa, Sugar, and Dry Milk Mixture, Water Added
1151430	Cocoa with Nf Dry Milk, Low Calorie Sweetener, Water Added
1151450	Cocoa with Whey, Low Calorie Sweetnr, Fortifd, Water Added
1151510	Cocoa and Sugar with Milk, Fortified, Puerto Rican
1151540	Cocoa with Nfdm, Low Calorie, Hi Calcium, Water Added
1151600	Cocoa, Whey, Low Calorie Sweetner Mix, Lowfat Milk Added
1151800	Milk Bev with Nf Dry Mlk, Low Calorie Sweet, Water, Choc
1151805	Milk Bev Withnf Dry Milk, Low Calorie Sweet,water,not Choc
1151810	Milk Bev Withnfd Milk, Low Calorie Sweet, Hi Calcium, Choc
1151900	Milk Beverage, Not Chocolate, with Whole Milk

1151905	Milk, Not Chocolate, Whole Milk Based
1151910	Milk Beverage, Beads, Whole Milk Added
1152000	Milk, Malted, Unfortified, Flavor Not Specified
1152100	Milk, Malted, Unfortified, Chocolate Flavor
1152101	Milk, Malted, Unfortified, Choc, Made with Skim Milk
1152200	Milk, Malted, Unfortified, Natural Flavor
1152500	Milk, Malted, Fortified, Natural Flavor (Includes Ovaltine)
1152600	Milk, Malted, Fortified, Chocolate (Includes Ovaltine)
1152700	Milk, Malted, Fortified, (Includes Ovaltine)
1153100	Eggnog, Made with Whole Milk (Includes Egg Nog, NFS)
1153150	Eggnog, Made with 2% Lowfat Milk
1153300	Eggnog, Beads, Reconstituted
1155105	Milk Fruit Drink (Includes Licuado)
1155110	Milk Fruit Drink, Hispanic Style
1155220	Milk-based Fruit Drink (Includes Orange Julius)
1156000	Choc-flavored Drink, Whey-&milk-based (includes Yoo-hoo)
1156002	Milk Drink, Whey&milk-base, Not Chocolate(Includes Yoo-hoo)
1156010	Flav'Milk Drink,skim Milk&cream-based,not Choc
1156011	Chocolate Flav Milk Drink, Skim Milk and Cream-based
1156101	Cafe Con Leche Prepared with Sugar

Ice Cream, Frozen Dairy Desserts and Novelties
(includes regular, soft-serve and sorbet)

Ice cream/ice milk
[erythritol] = 10 %

1311000	Ice Cream, NFS
1311010	Ice Cream, Regular, Not Chocolate
1311011	Ice Cream, Regular, Chocolate
1311012	Ice Cream, Rich, Flavors Other Than Chocolate
1311013	Ice Cream, Rich, Chocolate
1311020	Ice Cream, Soft Serve, Not Chocolate
1311021	Ice Cream, Soft Serve, Chocolate
1311040	Frzn Dairy Dessert,flavors Not Chocolate (No Butterfat)
1311045	Frozen Dairy Dessert, Chocolate (No Butterfat)
1312510	Ice Cream with Sherbet
1312600	Ice Cream, Fried
1313010	Ice Milk, NFS
1313030	Ice Milk, Regular, Not Chocolate
1313031	Ice Milk, Chocolate
1313035	Ice Milk, Premium, Flavors Other Than Choc
1313036	Ice Milk, Premium, Chocolate

1313060	Ice Milk, Soft Serve, Not Chocolate(Includes Frozen Custard)
1313061	Ice Milk, Soft Serve Chocolate(Tastee Freeze, Dairy Queen)
1314110	Ice Milk with Sherbet or Ice Cream
1315000	Sherbet, All Flavors
1314070	Ice Milk, Creamsicle or Dreamsicle
1314090	Ice Milk, Fudgesicle
1316000	Milk Dessert, Frozen, Made From Lowfat Milk
1316010	Milk Dessert, Frozen, Lowfat, with low Calorie Sweetener, not Chocolate
1316040	Milk Dessert, Frozen, Milk-fat Free, Not Chocolate
1316041	Milk Dessert, Frozen, Milk-fat Free, Chocolate
1316055	Milk Dessert, Frozen, Milk-fat Free, with Simplesse, Not Chocolate
1316056	Milk Dessert, Frozen, Milk-fat Free, with simplesse, Chocolate
6343010	Sorbet, Fruit, Noncitrus Flavor
6343011	Sorbet, Fruit, Citrus Flavor

Frozen novelties and desserts containing ice cream or ice milk

Ice cream bars/sandwiches (75 % for the ice cream)
[erythritol] = 7.5 %

1312005	Ice Cream Bar or Stick, Not Choc- or Cake-covered
1312010	Ice Cream Bar/stick, Chocolate Covered
1312011	Ice Cream Bar, Chocolate/Caramel Covered, with Nuts
1312012	Ice Cream Bar, Rich Chocolate Ice Cream, Thick Chocolate Cover
1312013	Ice Cream Bar/Stick, Rich Ice Cream, Chocolate Cover, with Nut
1312014	Ice Cream Bar/Stick, Chocolate Ice Cream, Chocolate Cover
1312030	Ice Cream Bar, Cake-covered
1312040	Ice Cream Bar/stick with Fruit
1312050	Ice Cream Sandwich
1312055	Ice Cream Cookie Sandwich (Includes Chipwich)
1313500	Ice Milk Sandwich (Includes Dairy Queen)
1314010	Ice Milk Bar or Stick, Chocolate-coated
1314011	Ice Milk Bar, Chocolate Covered, with Nuts (Includes Buster Bar)
1316100	Milk Dessert Bar, Frozen, Made From Lowfat Milk
1316150	Milk Dessert Sandwich Bar, Frozen, made From Lowfat Milk
1316152	Milk Dessert Sandwich Bar, Frozen, with low-calorie Sweetener, low fat
1316160	Milk Dessert Bar, Frozen, Lofat Milk and Low Calorie Sweetener
1316163	Ice Milk Bar/stick, with Low-calorie Sweetener, Chocolate Coat
9161105	Ice Pop Filled with Ice Cream, All Flavor Varieties

Ice cream cones (84% for the ice cream)
[erythritol] = 8.4%

1312070	Ice Cream Cone, with Nuts, Not Chocolate
1312071	Ice Cream Cone, Chocolate-covered, with Nuts, Not Choc
1312072	Ice Cream Cone, Chocolate-covered or Dipped, Not Choc
1312073	Ice Cream Cone, No Topping, Not Chocolate
1312074	Ice Cream Cone, No Topping, Not Specified as to Flavor
1312075	Ice Cream Cone, Withnuts, Chocolate Ice Cream
1312076	Ice Cream Cone, Chocolate-covered, Chocolate Ice Cream
1312077	Ice Cream Cone, No Topping, Chocolate Ice Cream
1312078	Ice Cream Cone, Chocolate-covered, Withnut, Chocolate Ice Cream
1312079	Ice Cream Sundae Cone (Includes Drumstick, All Flavors)

Ice milk cones (91% for ice milk)
[erythritol] = 9.1%

1313062	Ice Milk, Soft Serve Cone,not Chocolate(Includes Dairy Queen
1313063	Ice Milk, Soft Serve Cone, Chocolate
1314045	Ice Milk Cone, NFS
1314050	Ice Milk Cone, Not Chocolate
1314055	Ice Milk Cone, Chocolate

Ice cream sundaes (49.4% for the ice cream)
[erythritol] = 4.94%

1312100	Ice Cream Sundae, Topping Ns, with Whipped Cream
1312110	Ice Cream Sundae, Fruit Topping, with Whipped Cream
1312120	Ice Cream Sundae, Prepackaged, Not Chocolate
1312130	Ice Cream Sundae, Chocolate Topping, with Whipped Cream
1312140	Ice Cream Sundae, Not Fruit/ Chocolate Topping, with Whip Cream
1312150	Ice Cream Sundae, Fudge Topping, with Cake

Ice milk sundaes (61.3% for ice milk)
[erythritol] = 6.13%

1314060	Ice Milk Sundae, Soft Serve, Chocolate/Fudge Topping
1314063	Ice Milk Sundae, Soft Serve, Fruit Topping, with Whipping
1314065	Ice Milk Sundae, Soft Serve, Not Fruit/Chocolate Topping
1314066	Ice Milk Sundae, Chocolate/ Fudge Top (Without Whip Cream)
1314067	Ice Milk Sundae, Fruit Top (Without Whip Cream)
1314068	Ice Milk Sundae, No Fruit/ChocolateTop (Without Whip Cream)

Ice cream floats/milkshakes (26.7% for the ice cream)
[erythritol] = 2.67%

1154100	Milk Shake, Not Specified as to Flavor or Type
1154110	Milk Shake, Fountain Type, Not Specified as to Flavor
1154111	Milk Shake, Fountain Type, Chocolate
1154112	Milk Shake, Fountain Type, Not Chocolate
1154140	Milk Shake with Malt (Includes Malted Milk Withice Cream)
1154200	Thick Shake, Carry-out Type, Not Specified as to Flavor
1154210	Thick Shake, Carry-out Type, Chocolate
1154220	Thick Shake, Carry-out Type, Not Chocolate
1312080	Ice Cream Soda, Not Chocolate
1312081	Ice Cream Soda, Chocolate

Other desserts containing ice cream (64% for the ice cream)
[erythritol] = 6.4%

1312210	Ice Cream Pie, No Crust
1312250	Ice Cream Pie,cookie Crust,fudge Topping,whip Cream
1317000	Baked Alaska
5311200	Cake, Ice Cream and Cake Roll, Chocolate
5311210	Cake, Ice Cream and Cake Roll, Not Chocolate
5343030	Crepe, Dessert Type, Ice Cream-filled

Yogurt (Regular and Frozen)
[erythritol] = 10%

Regular yogurt
[erythritol] = 10%

1141101	Yogurt, Plain, Not Specified as to Type of Milk
1141110	Yogurt, Plain, Whole Milk
1141120	Yogurt, Plain, Lowfat Milk
1141130	Yogurt, Plain, Nonfat Milk
1142000	Yogurt, Vanilla, Lemon, Coffee, Not Specified as to Milk Type
1142100	Yogurt, Vanilla, Lemon, Coffee, Whole Milk
1142200	Yogurt, Vanilla, Lemon, Coffee, Lowfat Milk
1142300	Yogurt, Vanilla, Lemon, Coffee, Nonfat Milk
1142500	Yogurt, Chocolate, Not Specified as to Type of Milk
1142600	Yogurt, Chocolate, Whole Milk
1143000	Yogurt, Fruit Variety, Not Specified as to Milk Type
1143100	Yogurt, Fruit Variety, Whole Milk
1143200	Yogurt, Fruit Variety, Lowfat Milk

1143300	Yogurt, Fruit Variety, Nonfat Milk
1143350	Yogurt, Fruited, Nonfat Milk, Low Calorie Sweetener
1144400	Yogurt, Fruit and Nuts, Not Specified as to Type of Milk
1144500	Yogurt, Fruit and Nuts, Lowfat Milk
8311500	Yogurt Dressing

Frozen yogurt
[erthryitol] = 10%

1141000	Yogurt, Frozen Not Specified as to Type of Milk
1145999	Yogurt, Frozen, Not Specified as to Flavor, Not Specified to Type of Milk
1146000	Yogurt, Frozen, Not Chocolate, Type of Milk Not Specified
1146010	Yogurt, Frozen, Chocolate, Type of Milk Not Specified
1146016	Yogurt, Frozen, Chocolate, Lowfat Milk
1146017	Yogurt, Frozen, Not Chocolate, Lowfat Milk
1146020	Yogurt, Frozen, Chocolate, Nonfat Milk
1146030	Yogurt, Frozen, Not Chocolate, Nonfat Milk
1146040	Yogurt, Frozen, Chocolate, Nonfat Milk, with Low-calorie Sweetener
1146042	Yogurt, Frozen, Not Specified as to Flavor, Whole Milk
1146043	Yogurt, Frozen, Chocolate, Whole Milk
1146044	Yogurt, Frozen, Not Chocolate, Whole Milk
1146100	Yogurt, Frozen, Chocolate-coated
1146110	Yogurt, Frozen, Carob-coated
1146120	Yogurt, Frozen, Sandwich
1146125	Yogurt, Frozen, Cone, Chocolate
1146126	Yogurt, Frozen, Cone, Not Chocolate

Food products containing frozen yogurt (35.7% for frozen yogurt)
[erythritol]= 3.57%

5311215	Cake, Frozen Yogurt and Cake Layer, Not Chocolate, with Icing
5311216	Cake, Frozen Yogurt and Cake Layer, Chocolate, with Icing
5336600	Pie, Yogurt, Frozen

Table Top Sugar Substitutes
[erythritol] = 100% as carrier

9120000	Sugar Substitute, Low Calorie, Powdered, NFS
9120001	Sprinkle Sweet
9120002	Sugar Twin
9120003	Sugar Twin, Brown
9120004	Weight Watchers Sweet'ner, Sweet N' Low
9120005	Wee Cal

9120006	Saccharin
9120007	Sweet Magic Sugar Substitute
9120011	Sugar Substitute, Saccharin-based, Liquid
9120101	Aspartame Sweetener (Includes Equal)

Fat Cream in Cookies, Pastries and Cakes (60% erythritol in fat cream)(fat cream represents 35% of product)
[erythritol] = 21%

5116103	Roll, Sweet, with Fruit, Frosted, Diet
5310452	Cheesecake, Diet
5310457	Cheesecake, Diet, with Fruit
5310560	Cake, Chocolate/Devil's Food, Pudding Mix, Lite Recipe, with Icing
5310921	Cake, Cupcake, Not Chocolate, with Icing, Reduced Fat, No Cholesterol
5310927	Cupcake, Chocolate, with or without Icing, Fruit/cream Fill, Low Fat
5351150	Danish Pastry, with Cheese, Very Low Fat, No Cholesterol

Hard Candy (including pressed candy, mints and cough drops)
[erythritol] = 99%

9170001	Candy, NFS
9174502	Hard Candy
9174504	Butterscotch Hard Candy
9177000	Dietetic or Low Calorie Candy, NFS
9177002	Dietetic or Low Calorie Hard Candies
9177005	Mints, Dietetic or Low Calorie

Soft Candy (including non-chocolate, plain chocolate and chocolate coated)
[erythritol] = 60%

Non-chocolate
[erythritol] = 60%

9170001	Candy, NFS
9170201	Butterscotch Morsels
9170301	Caramel Candy, Chocolate-flavor Roll (Includes Tootsie Roll)
9170302	Caramel Candy, Not Chocolate
9170303	Caramel Candy, with Nuts
9170610	Coconut Candy, No Chocolate Covering
9170640	Coconut Candy, P.R. Style
9170700	Fondant Candy
9170800	Fruit Peel, Candied
9170801	Fruit Candy Bar

9170803	Fruit Leather (Includes Fruit Roll-up)
9170804	Fun Fruits Creme Supremes Candy
9171305	Fudge, Peanut Butter
9171306	Fudge, Peanut Butter, with Nuts
9171307	Fudge, Vanilla
9171308	Fudge, Vanilla, with Nuts
9171309	Fudge, Divinity
9171310	Fudge, Brown Sugar (Panuchi)
9171601	Halvah, Plain
9171800	Honey-combed Hard Candy, Peanut Butter
9171820	Jimmies (Includes Chocolate-flavored Sprinkles)
9172100	Licorice Candy
9172300	Marshmallows, Marshmallow Cream
9172302	Marshmallow, Candy-coated
9172305	Marshmallow, Coconut-coated
9172600	Nougat Candy, Plain
9172800	Nut Roll, Fudge or Nougat, Caramel and Nuts
9173200	Peanut Candy Bar
9173210	Planters Peanut Candy Bar
9173300	Peanut Brittle
9173350	Peanut Butter Boppers Candy Bar
9173405	P.b. Max Peanut Butter Snack
9173420	Reese's Pieces Candy
9173450	Peanut Butter Morsels Candy
9173500	Pralines
9173600	Pineapple Candy, P.R. Style
9174201	Sesame Crunch Candy (Sahadi)
9174501	Gumdrops
9174510	Skittles Candy
9175000	Taffy, Plain
9176000	Toffee, Plain
9176070	Wax Candy, Liquid Filled
9177001	Dietetic or Low Calorie Gumdrops

Plain chocolate
[erythritol] = 40%

9170501	Chocolate, Milk, Plain
9170520	Chocolate, Semi-sweet
9170521	Special Dark Candy
9170530	Chocolate Candy, Sweet or Dark
9170540	Chocolate Candy, White

9170550	Mexican Chocolate (Tablet)
9174601	Sugar-coated Chocolate Discs Candy

Plain chocolate with nuts (40% erythritol)(chocolate represents 84%)
[erythritol] = 33.6%

9170504	Chocolate, Milk, with Nuts, Not Almonds or Peanuts
9170505	Chocolate, Milk, with Fruits and Nuts (Includes Chunky)
9170506	Chocolate, Milk, with Almonds
9170507	Chocolate, Milk, with Peanuts (Includes Mr Goodbar)
9170541	Chocolate Candy, White, with Almonds

Chocolate coated (40% erythritol)(30% chocolate coating)
[erythritol] = 12%

9170050	"M&M's" Almond Chocolate Candies
9170101	Almonds, Chocolate-covered
9170304	Caramel Candy, Chocolate-covered
9170305	Caramel Candy, with Nuts and Cereal, Chocolate-covered
9170306	Caramel Candy, with Nuts, Chocolate-covered
9170307	Rolos Candy
9170310	Summit Cookie Bars
9170320	Twix Cookie Bars
9170325	Twix Chocolate Fudge Cookie Bars
9170330	Twix Peanut Butter Cookie Bars
9170335	Bar None Candy Bar
9170340	Whatchamacallit Candy
9170350	Nuts, Carob-coated
9170360	Espresso Coffee Beans, Chocolate-covered
9170405	Applause Candy
9170500	Chocolite Candy
9170502	Chocolate, Milk, with Cereal (Includes Krackel Bar)
9170503	Kit Kat Candy Bar
9170542	Chocolate, White, with Cereal, Candy
9170600	Coconut Candy, Chocolate-covered
9170701	Fondant Candy, Chocolate Covered
9170900	Fruit Candy, Chocolate-covered
9171301	Fudge, Chocolate, Chocolate-coated
9171302	Fudge, Chocolate, Chocolate-coated, with Nuts
9171500	Fudge, Caramel, with Nuts, Chocolate-coated
9171510	Snickers Candy Bar
9171511	Snickers Peanut Butter Bar
9171520	Baby Ruth Candy Bar

9171530	$100,000 Candy Bar
9171611	Halvah, Chocolate-covered
9171805	Honey-combed Candy, Peanut Butter, Choc-covered
9171810	Butterfinger Candy Bar
9172301	Marshmallow, Chocolate-covered
9172611	Nougat Candy, with Caramel, Chocolate-covered
9172613	Milky Way Candy Bar
9172614	Milky Way Dark Bar
9172615	Mars Bar
9172641	Nougat Candy, Chocolate-covered
9172642	3 Musketeers Candy Bar
9172701	Nuts, Chocolate-covered, Not Almonds or Peanuts
9173100	Peanuts, Chocolate-covered
9173101	M and M Peanut Candy
9173106	"M&m's" Peanut Butter Chocolate Candies
9173320	Peanut Bar, Chocolate Covered
9173400	Peanut Butter Candy, Chocolate-covered
9173410	Reese's Peanut Butter Cups
9173901	Raisins, Chocolate-covered
9173951	Raisins, Carob-covered
9174602	Royals Mint Chocolate Candy
9174610	"M and M's" Plain Chocolate Candies
9174612	Sixlets Candy
9174615	Easter Egg, Candy-coated Chocolate
9175011	Food Sticks, Fortified
9176010	Toffee, Chocolate Covered (Includes Heath Bar, Skor)
9176020	Toffee, Chocolate-coated, with Nuts
9176050	Truffles
9177003	Dietetic or Low Calorie Candy, Chocolate-covered

Chocolate with filling (60% erythritol)(70% filling)
[erythritol] = 42%

9170050	"M&M's" Almond Chocolate Candies
9170304	Caramel Candy, Chocolate-covered
9170305	Caramel Candy, with Nuts and Cereal, Chocolate-covered
9170306	Caramel Candy, with Nuts, Chocolate-covered
9170307	Rolos Candy
9170310	Summit Cookie Bars
9170320	Twix Cookie Bars
9170325	Twix Chocolate Fudge Cookie Bars
9170330	Twix Peanut Butter Cookie Bars
9170335	Bar None Candy Bar

9170340	Whatchamacallit Candy
9170405	Applause Candy
9170500	Chocolite Candy
9170502	Chocolate, Milk, with Cereal (Includes Krackel Bar)
9170503	Kit Kat Candy Bar
9170542	Chocolate, White, with Cereal, Candy
9170600	Coconut Candy, Chocolate-covered
9170701	Fondant Candy, Chocolate Covered
9170900	Fruit Candy, Chocolate-covered
9171301	Fudge, Chocolate, Chocolate-coated
9171302	Fudge, Chocolate, Chocolate-coated, with Nuts
9171303	Fudge, Chocolate
9171304	Fudge, Chocolate, with Nuts
9171500	Fudge, Caramel, with Nuts, Chocolate-coated
9171510	Snickers Candy Bar
9171511	Snickers Peanut Butter Bar
9171520	Baby Ruth Candy Bar
9171530	$100,000 Candy Bar
9171611	Halvah, Chocolate-covered
9171805	Honey-combed Candy, Peanut Butter, Choc-covered
9171810	Butterfinger Candy Bar
9172301	Marshmallow, Chocolate-covered
9172611	Nougat Candy, with Caramel, Chocolate-covered
9172613	Milky Way Candy Bar
9172614	Milky Way Dark Bar
9172615	Mars Bar
9172641	Nougat Candy, Chocolate-covered
9172642	3 Musketeers Candy Bar
9173101	M and M Peanut Candy
9173106	"M&m's" Peanut Butter Chocolate Candies
9173320	Peanut Bar, Chocolate Covered
9173350	Peanut Butter Boppers Candy Bar
9173400	Peanut Butter Candy, Chocolate-covered
9173410	Reese's Peanut Butter Cups
9174602	Royals Mint Chocolate Candy
9174610	"M and M's" Plain Chocolate Candies
9174612	Sixlets Candy
9174615	Easter Egg, Candy-coated Chocolate
9175011	Food Sticks, Fortified
9176010	Toffee, Chocolate Covered (Includes Heath Bar, Skor)
9176020	Toffee, Chocolate-coated, with Nuts
9176050	Truffles
9177003	Dietetic or Low Calorie Candy, Chocolate-covered

APPENDIX C

SUMMARY TABLES OF ERYTHRITOL CONSUMPTION ESTIMATES FOR INDIVIDUAL POPULATION GROUPS AND ERYTHRITOL USES/USDA CSFII FOOD CODES

Appendix C-1

Summary Tables of Erythritol Consumption Estimates For Individual Population Groups

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Table C-1 Estimated Daily per Person Erythritol Consumption by Males and Females Aged 0 to 12 Years from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean (g)	90th Percentile (g)	Mean (g)	90th Percentile (g)
Baked Goods and Baking Mixes						
	Bakery Fillings (fruit, custard, cream and pudding)	27.1	0.46	1.34	1.68	4.31
	Cakes and Cookies	49.9	1.60	4.79	3.20	7.11
	Fat Based Cream in Modified Fat/Low Calorie Cookies, Cakes and Pastries	0.2	0.02	na	6.63	7.63
Beverages and Beverage Mixes						
	Canned/Bottled Sugar Free and Low Calorie Carbonated and Noncarbonated Soft Drinks	12.2	0.66	2.10	5.40	11.10
Frozen Dairy Desserts and Mixes						
	Ice Cream, Frozen Dairy Desserts, and Novelties (regular ice cream, soft serve, sorbet, dry mixes)	31.1	1.47	4.43	4.72	9.98
Gelatins, Puddings and Fillings						
	Puddings (instant, phosphate set)	6.7	0.37	na	5.49	8.80

000174

Table C-1 Estimated Daily per Person Erythritol Consumption by Males and Females Aged 0 to 12 Years from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean (g)	90th Percentile (g)	Mean (g)	90th Percentile (g)
Hard Candy						
	Hard Candy (including pressed candies, mints and cough drops)	6.4	0.72	na	11.30	25.70
Milk Products						
	Dairy Drinks (chocolate milk and flavored milk beverages)	13.4	0.67	2.92	5.02	8.75
	Yogurt (regular and frozen)	8.4	0.56	na	6.67	12.90
Soft Candy						
	Soft Candy (including non-chocolate, plain chocolate and chocolate coated)	20.8	2.21	8.80	10.60	20.50
Sugar Substitutes						
	Tabletop Sweeteners (carrier for sugar substitutes)	1.3	0.01	na	0.81	1.33

000172

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Table C-2 Estimated Daily per Person Erythritol Consumption by Males and Females Aged 1 to 3 Years from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean (g)	90th Percentile (g)	Mean (g)	90th Percentile (g)
Baked Goods and Baking Mixes						
	Bakery Fillings (fruit, custard, cream and pudding)	21.7	0.20	0.51	0.91	2.41
	Cakes and Cookies	47.1	1.19	3.96	2.52	4.88
	Fat Based Cream in Modified Fat/Low Calorie Cookies, Cakes and Pastries	<0.01	na	na	na	Na
Beverages and Beverage Mixes						
	Canned/Bottled Sugar Free and Low Calorie Carbonated and Noncarbonated Soft Drinks	0.1	0.54	na	5.53	16.80
Frozen Dairy Desserts and Mixes						
	Ice Cream, Frozen Dairy Desserts, and Novelties (regular ice cream, soft serve, sorbet, dry mixes)	27.2	0.99	4.00	3.66	6.65
Gelatins, Puddings and Fillings						
	Puddings (instant, phosphate set)	6.7	0.34	na	5.16	8.70

000173

Table C-2 Estimated Daily per Person Erythritol Consumption by Males and Females Aged 1 to 3 Years from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean (g)	90th Percentile (g)	Mean (g)	90th Percentile (g)
Hard Candy						
	Hard Candy (including pressed candies, mints and cough drops)	4.9	0.44	na	8.91	18.10
Milk Products						
	Dairy Drinks (chocolate milk and flavored milk beverages)	4	0.24	na	6.11	14.60
	Yogurt (regular and frozen)	10.2	0.70	2.55	6.82	11.40
Soft Candy						
	Soft Candy (including non-chocolate, plain chocolate and chocolate coated)	19	1.95	6.66	10.20	18.70
Sugar Substitutes						
	Tabletop Sweeteners (carrier for sugar substitutes)	1.2	0.01	na	1.12	2.67

000174

Table C-3 Estimated Daily per Person Erythritol Consumption by Males and Females Age Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption	
			Mean (g)	90th Percentile (g)
Baked Goods and Baking Mixes				
	Bakery Fillings (fruit, custard, cream and pudding)	25.8	0.56	1.75
	Cakes and Cookies	46.3	2.00	6.72
	Fat Based Cream in Modified Fat/Low Calorie Cookies, Cakes and Pastries	0.7	0.07	na
Beverages and Beverage Mixes				
	Canned/Bottled Sugar Free and Low Calorie Carbonated and Noncarbonated Soft Drinks	21.0	2.00	7.13
Frozen Dairy Desserts and Mixes				
	Ice Cream, Frozen Dairy Desserts, and Novelties (regular ice cream, soft serve, sorbet, dry mixes)	31.4	2.14	7.40
Gelatins, Puddings and Fillings				
	Puddings (instant, phosphate set)	3.8	0.24	na
Hard Candy	Hard Candy (including pressed candies, mints and cough drops)	4.7	0.49	na

Table C-3 Estimated Daily per Person Erythritol Consumption by Males and Females Aged 13 to 18 Years from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean* (g)	90th Percentile (g)	Mean (g)	90th Percentile (g)
Milk Products						
	Dairy Drinks (chocolate milk and flavored milk beverages)	12.0	0.81	2.92	6.77	12.30
	Yogurt (regular and frozen)	4.0	0.28	na	7.08	12.90
Soft Candy						
	Soft Candy (including non-chocolate, plain chocolate and chocolate coated)	19.2	2.96	11.40	15.40	32.40
Sugar Substitutes						
	Tabletop Sweeteners (carrier for sugar substitutes)	2.9	0.02	na	0.87	1.67

000176

Table C-4 Estimated Daily per Person Erythritol Consumption by Males and Females Aged 19 to 65 Years from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean (g)	90th Percentile (g)	Mean (g)	90th Percentile (g)
Baked Goods and Baking Mixes						
	Bakery Fillings (fruit, custard, cream and pudding)	22.2	0.69	2.05	3.11	7.85
	Cakes and Cookies	36.3	1.66	5.59	4.57	10.00
	Fat Based Cream in Modified Fat/Low Calorie Cookies, Cakes and Pastries	0.1	<0.01	na	6.97	15.30
Beverages and Beverage Mixes						
	Canned/Bottled Sugar Free and Low Calorie Carbonated and Noncarbonated Soft Drinks	27.9	3.36	12.40	12.00	25.20
Frozen Dairy Desserts and Mixes						
	Ice Cream, Frozen Dairy Desserts, and Novelties (regular ice cream, soft serve, sorbet, dry mixes)	24.1	1.39	4.43	5.79	11.70
Gelatins, Puddings and Fillings						
	Puddings (instant, phosphate set)	3.1	0.21	na	6.60	13.10

0001277

Table C-4 Estimated Daily per Person Erythritol Consumption by Males and Females Aged 19 to 65 Years from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean* (g)	90th Percentile (g)	Mean (g)	90th Percentile (g)
Hard Candy						
	Hard Candy (including pressed candies, mints and cough drops)	1.9	0.16	na	8.11	18.70
Milk Products						
	Dairy Drinks (chocolate milk and flavored milk beverages)	4.5	0.24	na	5.26	9.48
	Yogurt (regular and frozen)	8.7	0.87	na	10.00	20.40
Soft Candy						
	Soft Candy (including non-chocolate, plain chocolate and chocolate coated)	15.3	1.73	6.27	11.30	22.00
Sugar Substitutes						
	Tabletop Sweeteners (carrier for sugar substitutes)	9.6	0.16	na	1.64	3.60

000128

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Table C-5 Estimated Daily per Person Erythritol Consumption by the Total U.S. Population from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean (g)	90th Percentile (g)	Mean (g)	90th Percentile (g)
Baked Goods and Baking Mixes						
	Bakery Fillings (fruit, custard, cream and pudding)	24.1	0.67	1.96	2.78	6.86
	Cakes and Cookies	40.9	1.69	5.50	4.13	9.00
	Fat Based Cream in Modified Fat/Low Calorie Cookies, Cakes and Pastries	0.2	0.01	na	7.65	10.30
Beverages and Beverage Mixes						
	Canned/Bottled Sugar Free and Low Calorie Carbonated and Noncarbonated Soft Drinks	22.9	2.46	8.40	10.70	23.70
Frozen Dairy Desserts and Mixes						
	Ice Cream, Frozen Dairy Desserts, and Novelties (regular ice cream, soft serve, sorbet, dry mixes)	26.6	1.49	5.17	5.62	11.50
Gelatins, Puddings and Fillings						
	Puddings (instant, phosphate set)	4.1	0.25	na	6.21	10.20

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Table C-5 Estimated Daily per Person Erythritol Consumption by the Total U.S. Population from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean* (g)	90th Percentile (g)	Mean (g)	90th Percentile (g)
Hard Candy						
	Hard Candy (including pressed candies, mints and cough drops)	3.0	0.30	na	9.96	22.80
Milk Products						
	Dairy Drinks (chocolate milk and flavored milk beverages)	6.8	0.36	na	5.37	11.70
	Yogurt (regular and frozen)	8.2	0.74	na	9.06	17.00
Soft Candy						
	Soft Candy (including non-chocolate, plain chocolate and chocolate coated)	16.4	1.84	6.72	11.30	21.10
Sugar Substitutes						
	Tabletop Sweeteners (carrier for sugar substitutes)	8.3	0.13	na	1.56	3.33

000180

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Table C-6 Estimated Daily per Kilogram Body Weight Erythritol Consumption by Males and Females Aged 0 to 12 Years from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean (g/kg)	90th Percentile (g/kg)	Mean (g/kg)	90yh Percentile (g/kg)
Baked Goods and Baking Mixes						
	Bakery Fillings (fruit, custard, cream and pudding)	27.1	0.02	0.05	0.06	0.18
	Cakes and Cookies	49.9	0.07	0.20	0.14	0.30
	Fat Based Cream in Modified Fat/Low Calorie Cookies, Cakes and Pastries	0.2	<0.01	na	0.32	0.48
Beverages and Beverage Mixes						
	Canned/Bottled Sugar Free and Low Calorie Carbonated and Noncarbonated Soft Drinks	12.2	0.03	0.08	0.22	0.43
Frozen Dairy Desserts and Mixes						
	Ice Cream, Frozen Dairy Desserts, and Novelties (regular ice cream, soft serve, sorbet, dry mixes)	31.1	0.06	0.22	0.19	0.39
Gelatins, Puddings and Fillings						
	Puddings (instant, phosphate set)	6.7	0.02	na	0.25	0.44

000181

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Table C-6 Estimated Daily per Kilogram Body Weight Erythritol Consumption by Males and Females Aged 0 to 12 Years from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean* (g/kg)	90th Percentile (g/kg)	Mean (g/kg)	90yh Percentile (g/kg)
Hard Candy						
	Hard Candy (including pressed candies, mints and cough drops)	6.4	0.03	na	0.45	1.08
Milk Products						
	Dairy Drinks (chocolate milk and flavored milk beverages)	13.4	0.02	0.09	0.18	0.34
	Yogurt (regular and frozen)	8.3	0.02	na	0.33	0.66
Soft Candy						
	Soft Candy (including non-chocolate, plain chocolate and chocolate coated)	20.8	0.10	0.34	0.47	1.09
Sugar Substitutes						
	Tabletop Sweeteners (carrier for sugar substitutes)	1.3	<0.01	na	0.04	0.08

000182

Table C-7 Estimated Daily per Kilogram Body Weight Erythritol Consumption by Males and Females Aged 1 to 3 Years from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean (g/kg)	90th Percentile (g/kg)	Mean (g/kg)	90th Percentile (g/kg)
Baked Goods and Baking Mixes						
	Bakery Fillings (fruit, custard, cream and pudding)	21.7	0.01	0.04	0.06	0.02
	Cakes and Cookies	47.1	0.08	0.27	0.18	0.37
	Fat Based Cream in Modified Fat/Low Calorie Cookies, Cakes and Pastries	<0.01	<0.01	na	na	na
Beverages and Beverage Mixes						
	Canned/Bottled Sugar Free and Low Calorie Carbonated and Noncarbonated Soft Drinks	0.1	0.04	na	0.38	1.03
Frozen Dairy Desserts and Mixes						
	Ice Cream, Frozen Dairy Desserts, and Novelties (regular ice cream, soft serve, sorbet, dry mixes)	27.2	0.07	0.25	0.26	0.51
Gelatins, Puddings and Fillings						
	Puddings (instant, phosphate set)	6.7	0.02	na	0.37	0.66

000183

Table C-7 Estimated Daily per Kilogram Body Weight Erythritol Consumption by Males and Females Aged 1 to 3 Years from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean* (g/kg)	90th Percentile (g/kg)	Mean (g/kg)	90th Percentile (g/kg)
Hard Candy						
	Hard Candy (including pressed candies, mints and cough drops)	4.9	0.03	na	0.61	1.26
Milk Products						
	Dairy Drinks (chocolate milk and flavored milk beverages)	4.0	0.01	na	0.34	0.90
	Yogurt (regular and frozen)	10.2	0.05	0.07	0.48	0.82
Soft Candy						
	Soft Candy (including non-chocolate, plain chocolate and chocolate coated)	19.0	0.15	0.45	0.78	1.70
Sugar Substitutes						
	Tabletop Sweeteners (carrier for sugar substitutes)	1.2	<0.01	na	0.07	0.01

000184

Table C-8 Estimated Daily per Kilogram Body Weight Erythritol Consumption by Males and Females Aged 13 to 18 Years from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean (g/kg)	90th Percentile (g/kg)	Mean (g/kg)	90th Percentile (g/kg)
Baked Goods and Baking Mixes						
	Bakery Fillings (fruit, custard, cream and pudding)	25.8	<0.01	0.03	0.04	0.09
	Cakes and Cookies	46.3	0.03	0.11	0.07	0.17
	Fat Based Cream in Modified Fat/Low Calorie Cookies, Cakes and Pastries	0.7	<0.01	na	0.15	0.16
Beverages and Beverage Mixes						
	Canned/Bottled Sugar Free and Low Calorie Carbonated and Noncarbonated Soft Drinks	21.0	0.03	0.12	0.16	0.31
Frozen Dairy Desserts and Mixes						
	Ice Cream, Frozen Dairy Desserts, and Novelties (regular ice cream, soft serve, sorbet, dry mixes)	31.4	0.04	0.13	0.11	0.20
Gelatins, Puddings and Fillings						
	Puddings (instant, phosphate set)	3.8	<0.01	na	0.10	0.17

000185

Table C-8 Estimated Daily per Kilogram Body Weight Erythritol Consumption by Males and Females Aged 13 to 18 Years from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean* (g/kg)	90th Percentile (g/kg)	Mean (g/kg)	90th Percentile (g/kg)
Hard Candy						
	Hard Candy (including pressed candies, mints and cough drops)	4.7	0.01	na	0.22	0.57
Milk Products						
	Dairy Drinks (chocolate milk and flavored milk beverages)	12	0.01	0.05	0.12	0.22
	Yogurt (regular and frozen)	4	<0.01	na	0.12	0.20
Soft Candy						
	Soft Candy (including non-chocolate, plain chocolate and chocolate coated)	19.2	<0.01	0.20	0.27	0.57
Sugar Substitutes						
	Tabletop Sweeteners (carrier for sugar substitutes)	2.9	<0.01	na	0.01	0.03

000186

Table C-9 Estimated Daily per Kilogram Body Weight Erythritol Consumption by Males and Females Aged 19 to 65 Years from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean (g/kg)	90th Percentile (g/kg)	Mean (g/kg)	90th Percentile (g/kg)
Baked Goods and Baking Mixes						
	Bakery Fillings (fruit, custard, cream and pudding)	22.2	<0.01	0.03	0.04	0.10
	Cakes and Cookies	36.3	0.02	0.08	0.06	0.14
	Fat Based Cream in Modified Fat/Low Calorie Cookies, Cakes and Pastries	0.1	<0.01	na	0.10	0.20
Beverages and Beverage Mixes						
	Canned/Bottled Sugar Free and Low Calorie Carbonated and Noncarbonated Soft Drinks	27.9	0.05	0.16	0.17	0.35
Frozen Dairy Desserts and Mixes						
	Ice Cream, Frozen Dairy Desserts, and Novelties (regular ice cream, soft serve, sorbet, dry mixes)	24.1	0.02	0.07	0.08	0.16
Gelatins, Puddings and Fillings						
	Puddings (instant, phosphate set)	3.1	<0.01	na	0.09	0.16

000187

Table C-9 Estimated Daily per Kilogram Body Weight Erythritol Consumption by Males and Females Aged 19 to 65 Years from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean* (g/kg)	90th Percentile (g/kg)	Mean (g/kg)	90th Percentile (g/kg)
Hard Candy						
	Hard Candy (including pressed candies, mints and cough drops)	1.9	<0.01	na	0.12	0.30
Milk Products						
	Dairy Drinks (chocolate milk and flavored milk beverages)	4.5	<0.01	na	0.07	0.14
	Yogurt (regular and frozen)	8.7	0.01	na	0.15	0.30
Soft Candy						
	Soft Candy (including non-chocolate, plain chocolate and chocolate coated)	15.3	0.02	0.09	0.16	0.32
Sugar Substitutes						
	Tabletop Sweeteners (carrier for sugar substitutes)	9.6	<0.01	na	0.02	0.05

000188

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Table C-10 Estimated Daily per Kilogram Body Weight Erythritol Consumption by the Total U.S. Population from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean (g/kg)	90th Percentile (g/kg)	Mean (g/kg)	90th Percentile (g/kg)
Baked Goods and Baking Mixes						
	Bakery Fillings (fruit, custard, cream and pudding)	24.1	0.01	0.03	0.05	0.11
	Cakes and Cookies	40.9	0.03	0.1	0.08	0.18
	Fat Based Cream in Modified Fat/Low Calorie Cookies, Cakes and Pastries	0.2	<0.01	na	0.17	0.31
Beverages and Beverage Mixes						
	Canned/Bottled Sugar Free and Low Calorie Carbonated and Noncarbonated Soft Drinks	22.9	0.04	0.13	0.17	0.34
Frozen Dairy Desserts and Mixes						
	Ice Cream, Frozen Dairy Desserts, and Novelties (regular ice cream, soft serve, sorbet, dry mixes)	26.6	0.03	0.10	0.11	0.24
Gelatins, Puddings and Fillings						
	Puddings (instant, phosphate set)	4.1	<0.01	na	0.14	0.28

000189

Table C-10 Estimated Daily per Kilogram Body Weight Erythritol Consumption by the Total U.S. Population from Individual Current and Expanded Food-uses

Food Category	Food Product	% Users	All-Person Consumption		All-Users Consumption	
			Mean* (g/kg)	90th Percentile (g/kg)	Mean (g/kg)	90th Percentile (g/kg)
Hard Candy						
	Hard Candy (including pressed candies, mints and cough drops)	3.0	<0.01	na	0.28	0.68
Milk Products						
	Dairy Drinks (chocolate milk and flavored milk beverages)	6.8	<0.01	na	0.12	0.26
	Yogurt (regular and frozen)	8.2	0.02	na	0.18	0.38
Soft Candy						
	Soft Candy (including non-chocolate, plain chocolate and chocolate coated)	16.4	0.04	0.12	0.25	0.54
Sugar Substitutes						
	Tabletop Sweeteners (carrier for sugar substitutes)	8.3	<0.01	na	0.02	0.05

0001390

APPENDIX D

APPENDIX D

MARKETSHARE CONSIDERATIONS

Table D-1 Summary of Estimated Erythritol Consumption by Different Population Groups from Current and Expanded Uses Without Beverages Using USDA CFS II 1989-91

Population Group	% Users	All-Person Consumption g/day (mg/kg bw/day)		All-Users Consumption g/day (mg/kg bw/day)	
		Mean	90th Percentile	Mean	90th Percentile
Total population	68.1	6.98 (142)	19.30 (377)	10.20 (209)	23.00 (465)
Male and Females Aged 0-12 Years	71.6	7.41 (317)	20.20 (857)	10.30 (442)	23.60 (997)
Male and Females Aged 1-3 Years	69.5	5.82 (421)	18.7 (1300)	8.37 (605)	20.2 (1450)
Male and Females Aged 13-18 Years	73.5	10.90 (187)	28.80 (503)	14.80 (255)	34.80 (604)
Male and Females Aged 19-65 Years	65	6.87 (96)	19.40 (276)	10.60 (148)	23.80 (332)

000193

Normalization of Erythritol Intakes from the USDA CSFII Food Consumption Database to Combine Marketshare Adjusted Estimates from all Other Proposed Food Categories with NonAdjusted Estimates from Beverages Including Canned/Bottled Carbonated and Noncarbonated Soft Drinks, and Dairy Drinks

I. Users-only average, total population group.

Sum of separate average erythritol intakes for 9 food groups (see Appendix C, Table C-5) is 58.27 grams per day (g/d). Correction of the consumption of each individual group for 20% market share results in a total of 11.65 g/day. Mean users erythritol consumption from canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks (Table C-5) is 16.07 g/day. The sum of the market share corrected other food categories and all beverages including canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks is 27.72 g/day.

The normalized total erythritol consumption from all proposed for categories is

$$\frac{(27.72)}{11.65} \times (2.04)\ g = 4.85\ g/day$$

II. Users-only 90th percentile, total population group.

Sum of separate average erythritol intakes for 9 food groups (See Appendix C, Table C-5) is 112.09 grams per day (g/d). Correction of the consumption of each individual group for 20% market share results in a total of 22.42 g/day. Heavy users (90th percentile) erythritol consumption from canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks (Table C-5) is 35.40 g/day. The sum of the market share corrected other food categories and all beverages from canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks is 57.82 g/day.

The normalized total erythritol consumption from all proposed for categories is

$$\frac{(57.82)}{22.42} \times (4.60)\ g = 11.86\ g/day$$

Normalization of Erythritol Intakes from the USDA CSFII Food Consumption Database to Combine Marketshare Adjusted Estimates from All Other Proposed Food Categories with NonAdjusted Estimates from Beverages Including Canned/Bottled Carbonated and Noncarbonated Soft Drinks and Dairy Drinks

I. Users-only average, male and females aged 1 to 3 years.

Sum of separate average erythritol intakes for 9 food groups (see Appendix C, Table C-2) is 39.30 grams per day (g/d). Correction of the consumption of each individual group for 20% market share results in a total of 7.86 g/day. Mean users erythritol consumption from canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks (Table C-2) is 11.64 g/day. The sum of the market share corrected other food categories and all beverages including canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks is 19.50 g/day.

The normalized total erythritol consumption from all proposed for categories is

$$\frac{(19.50)}{7.86} \times (1.67)\ g = 4.14\ g/day$$

II. Users-only 90th percentile, male and females aged 1 to 3 years.

Sum of separate average erythritol intakes for 9 food groups (See Appendix C, Table C-2) is 73.51 grams per day (g/d). Correction of the consumption of each individual group for 20% market share results in a total of 14.70 g/day. Heavy users (90th percentile) erythritol consumption from canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks (Table C-2) is 31.40g/day. The sum of the market share corrected other food categories and all beverages from canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks is 46.10 g/day.

The normalized total erythritol consumption from all proposed for categories is

$$\frac{(46.10)}{14.70} \times (4.04)\ g = 12.67\ g/day$$

Normalization of Erythritol Intakes from the USDA CSFII Food Consumption Database to Combine Marketshare Adjusted Estimates from all Other Proposed Food Categories with NonAdjusted Estimates from Beverages Including Canned/Bottled Carbonated and Noncarbonated Soft Drinks and Dairy Drinks

I. Users-only average, males and females aged 0 to 12 years

Sum of separate average erythritol intakes for 9 food groups (See Appendix C, Table C-1) is 51.10 grams per day (g/d). Correction of the consumption of each individual group for 20% market share results in a total of 10.22 g/day. Mean users erythritol consumption from canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks (Table C-1) is 10.42 g/day. The sum of the market share corrected other food categories and all beverages including canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks is 20.64 g/day.

The normalized total erythritol consumption from all proposed for categories is

$$\frac{(20.64)}{10.22} \times (2.06)\ g = 4.16\ g/day$$

II. Users-only 90th percentile, males and females aged 0 to 12 years

Sum of separate average erythritol intakes for 9 food groups (See Appendix C, Table C-1) is 98.26 grams per day (g/d). Correction of the consumption of each individual group for 20% market share results in a total of 19.65 g/day. Heavy users (90th percentile) erythritol consumption from canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks (Table C-1) is 19.85 g/day. The sum of the market share corrected other food categories and all beverages from canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks is 39.50 g/day.

The normalized total erythritol consumption from all proposed for categories is

$$\frac{(39.50)}{19.65} \times (4.72)\ g = 9.49\ g/day$$

Normalization of Erythritol Intakes from the USDA CSFII Food Consumption Database to Combine Marketshare Adjusted Estimates from all Other Proposed Food Categories with NonAdjusted Estimates from Beverages Including Canned/Bottled Carbonated and Noncarbonated Soft Drinks and Dairy Drinks

I. Users-only average, males and females aged 13 to 18 years

Sum of separate average erythritol intakes for 9 food groups (See Appendix C, Table C-3) is 63.10 grams per day (g/d). Correction of the consumption of each individual group for 20% market share results in a total of 12.62 g/day. Mean users erythritol consumption from canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks (Table C-3) is 16.08 g/day. The sum of the market share corrected other food categories and all beverages including canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks is 28.70 g/day.

The normalized total erythritol consumption from all proposed for categories is

$$\frac{(28.70)}{12.62} \times (2.96)\ g = 6.73\ g/day$$

II. Users-only 90th percentile, males and females aged 13 to 18 years

Sum of separate average erythritol intakes for 9 food groups (See Appendix C, Table C-3) is 110.23 grams per day (g/d). Correction of the consumption of each individual group for 20% market share results in a total of 22.05 g/day. Heavy users (90th percentile) erythritol consumption from canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks (Table C-3) is 30.50 g/day. The sum of the market share corrected other food categories and all beverages from canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks is 52.55 g/day.

The normalized total erythritol consumption from all proposed for categories is

$$\frac{(52.55)}{22.05} \times (6.96)\ g = 16.59\ g/day$$

Normalization of Erythritol Intakes from the USDA CSFII Food Consumption Database to Combine Marketshare Adjusted Estimates from all Other Proposed Food Categories with NonAdjusted Estimates from Beverages Including Canned/Bottled Carbonated and Noncarbonated Soft Drinks and Dairy Drinks

I. Users-only average, males and females aged 19 to 65 years.

Sum of separate average erythritol intakes for 9 food groups (See Appendix C, Table C-4) is 58.09 grams per day (g/d). Correction of the consumption of each individual group for 20% market share results in a total of 11.62 g/day. Mean users erythritol consumption from canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks (Table C-4) is 17.26 g/day. The sum of the market share corrected other food categories and all beverages including canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks is 28.88 g/day.

The normalized total erythritol consumption from all proposed for categories is

$$\frac{(28.88)}{11.62} \times (2.12)\ g = 5.27\ g/day$$

II. Users-only 90th percentile, males and females aged 19 to 65 years.

Sum of separate average erythritol intakes for 7 food groups (See Appendix C, Table C-3) is 122.65 grams per day (g/d). Correction of the consumption of each individual group for 20% market share results in a total of 24.53 g/day. Heavy users (90th percentile) erythritol consumption from canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks (Table C-4) is 34.68 g/day. The sum of the market share corrected other food categories and all beverages from canned/bottled carbonated and noncarbonated soft drinks, and dairy drinks is 59.21 g/day.

The normalized total erythritol consumption from all proposed for categories is

$$\frac{(59.21)}{24.53} \times (4.76)\ g = 11.49\ g/day$$

APPENDIX E

APPENDIX E

REFERENCES

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

January 15, 1997

Ms. Diane B. McColl, Esquire
Hyman, Phelps & McNamara, P.C.
700 Thirteenth St. NW, Suite 1200
Washington, DC 200050

Re: GRAS Affirmation Petition No. 7G0422 - Erythritol for use as a human food ingredient

Dear Ms. McColl:

This is in reference to the petition of Cerestar Holding Co., B.V., Mitsubish Chemical Corporation, and Nikken Chemicals Co., Ltd. proposing to affirm that erythritol is generally recognized as safe (GRAS) as an ingredient in human food.

Our preliminary administrative review indicates that the petition meets the requirements for consideration under 21 CFR 170.30 and 170.35 and the petition has been filed. The date of this letter is the filing date of your petition. There is no pre-filing review of the adequacy of the data to support a GRAS conclusion. Thus, the filing of this petition should not be interpreted as a preliminary indication that the use of erythritol in food is GRAS.

Sincerely yours,

Rosalie M. Angeles, Ph.D.
Division of Product Policy, HFS-205
Center for Food Safety
and Applied Nutrition

000222

Food and Drug Administration

[Docket No. 97G-0063]

Cerestar Holding Co. B.V., Mitsubishi Chemical Corp., and Nikken Chemicals Co., Ltd.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Cerestar Holding Co. B.V., Mitsubishi Chemical Corp., and Nikken Chemicals Co., Ltd., have filed a petition (GRASP 7G0422) proposing to affirm that the use of erythritol is generally recognized as safe (GRAS) as an ingredient in human food.

DATES: Written comments by May 20, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rosalie M. Angeles, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3107.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s) and 409(b)(5) (21 U.S.C. 321(s) and 348(b)(5)) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that Cerestar Holding Co. B.V., Mitsubishi Chemical Corp., and Nikken Chemicals Co., Ltd., c/o Hyman, Phelps & McNamara, 700 13th St. NW., suite 1200, Washington, DC 20005, have filed a petition (GRASP 7G0422) proposing that erythritol be affirmed as GRAS for use as an ingredient in human food.

The petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in §§ 170.30 (21 CFR 170.30) and 170.35 is filed by the agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Interested persons may, on or before May 20, 1997, review the petition and file comments with the Dockets Management Branch (address above). Two copies of any comments should be filed and should be identified with the docket number found in brackets in the heading of this document. Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS for the proposed use. In addition, consistent with the regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency encourages public participation by review of and comment on the environmental assessment submitted with the petition that is the subject of this notice. A copy of the petition (including the environmental assessment) and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 12, 1997.

George H. Pauli,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 97-5454 Filed 3-5-97; 8:45 am]

BILLING CODE 4160-01-F

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94MGF00162 362

MAFF Food Safety Directorate

food surveillance

NUMBER 46 November 1994 INFORMATION SHEET

SURVEY OF THE INTAKE OF SWEETENERS BY DIABETICS

Summary

MAFF has recently carried out a survey of intakes by diabetics of the four intense sweeteners (acesulfame K, aspartame, saccharin and thaumatin) and six bulk sweeteners (hydrogenated glucose syrup, isomalt, lactitol, mannitol, sorbitol and xylitol) currently permitted in the UK. Initial results show that intakes are within the acceptable limits.

Background

Diabetics need to control their intake of sugars and it is therefore particularly useful for them to have alternative sweetening agents available. The sweeteners permitted under the 1983 Sweeteners in Food Regulations (as amended) may be used in diabetic foods as alternatives to glucose and sucrose, allowing diabetics to consume a wider range of sweetened foods. In addition diabetics may also use low calorie, sugar-free or diet products. Since diabetics may thereby be exposed to higher than average amounts of sweeteners for a long period it is important to check that intakes remain within acceptable limits and cause no adverse effect on their health.

Intakes of sweeteners by both the general population and a selected population of diabetics were examined in 1987 and 1988 respectively and the results published in Food Surveillance Paper No. 29 (1990). The results were also considered by MAFF's Food Advisory Committee (FAC) and the Department of Health's Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT). Although the results of these surveys were thought to be generally reassuring a few people, notably diabetics, were found to exceed the Acceptable Daily Intake (ADI) for one of the intense sweeteners, saccharin. Following advice from the FAC, Ministers announced an initiative to reduce these intakes of saccharin through an advisory leaflet and voluntary labelling of saccharin based table-top sweeteners used in tea and coffee. In addition, the FAC recommended that a fuller survey be carried out to obtain more accurate information on the sweetener intake of the British diabetic population and to monitor changes in their diet resulting from the introduction of newer sweeteners on the market.

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Survey

The survey was carried out by the University of Southampton. In order to ensure that the survey was as wide-ranging as possible, diabetics were studied across the full age range from 2- 65 years and over. The study was also constructed so as to give a model of the British diabetic population as a whole.

The consumption of foods by diabetics was determined using a Food Frequency Questionnaire which had three components:

(i) A structured interview on meal patterns;
(ii) Recall of food intake; and
(iii) A food checklist on usual consumption.

The food checklist contained 37 foods likely to contain sweeteners together with 70 other foods to disguise the purpose of the survey. The main classes of sweetener-containing foods consumed by those individuals who participated in the survey were beverages, dairy products, confectionery, savoury sauces, canned products, biscuits, cakes, desserts, prepared salads, jams, marmalades and table top sweeteners for use in tea and coffee. Care was taken to ensure that the consumption data were recorded in sufficient detail (food type, brand and flavour) so that products could be accurately matched to sweetener concentration information.

The results of the food frequency questionnaire were validated by comparing its predictions against actual consumption determined by a seven day weighed record. This validation study was performed using 50 selected diabetics whose demographic profile reflected the range of the survey. The results of the validation study showed good overall agreement between the predictions of the food frequency questionnaire and the weighed record.

The recruitment and interviewing of the participants involved in the main survey took place mostly during the spring of 1994. The low incidence of diabetes among children has meant that recruitment in the younger age groups has been slower than had been hoped and further work is still continuing. However results are currently available for a total of 761 participants.

In order to calculate the intake of the sweeteners by diabetics it was necessary for a sweetener concentration database to be constructed. This was done by asking food manufacturers to supply information on the concentration of sweeteners used in their products. This information was combined with the food consumption data from the food frequency questionnaire to give intakes of sweeteners for each participant in the survey.

Results

The results for the intense sweeteners show that intakes exceed the ADI for just one sweetener (saccharin) and then only by a very small proportion of individuals (5 members out of a survey population of 761, i.e. less than 1%). Using data on the nationwide prevalence of diabetes it has been possible to calculate preliminary results for a representative British diabetic population. High level intakes of each intense sweetener as measured by the 97.5th percentile are all within acceptable limits, see table 1. The 97.5th percentile level of consumption is generally taken to be representative of the upper limit of normal dietary behaviour. The intense sweetener thaumatin was not encountered during the survey.

The polyol sweeteners have been classified by the COT as acceptable for use in food, and by the EC's Scientific Committee for Food (SCF) as ADI "not specified". ADI's have not been set because the polyol sweeteners are of such low toxicity that their maximum potential intake is not considered to be an identifiable hazard to health. However because the polyol sweeteners and the carbohydrate fructose may have a laxative effect it is recommended that diabetics do not exceed a combined intake of 25g per day. The survey results show that the average intake of polyols by the survey population was 2g per day, although a small proportion of individuals (13 members out of a survey population 761, i.e. less than 2%) did consume in excess of the recommended level. However, there is evidence that the tolerance to polyols may vary quite markedly from individual to individual and that the laxative effect is dependent on the type of polyol, the nature of the food product and the quantity consumed at any one time.

Contact Point

For further information please contact:

Dr Esther Heller
MAFF, Additives and Novel Foods Division
Rm 225, Ergon House c/o Nobel House
17 Smith Square
London SW1P 3JR.

Tel: 0171 238 6234,
Fax: 0171 238 5331.

Intake of intense and bulk sweeteners in the U.K 1994-1995.
(unpublished but is expected to be published shortly)

TABLE 1

INTAKES OF BULK SWEETENERS (g/day)

Sweetener	Per cent of population consuming	Median g/day	Maximu mg/day
Sorbitol	45	1.0	52.8
Mannitol	32	0.1	3.1
Xylitol	14	0.3	6.2
Isomalt	23	0.9	13.8
Maltitol syrup	33	0.17	7.5
Lactitol	3	0.4	4.1

Note: The median is calculated for consumers of the sweetener only.

TABLE 2

DAILY INTAKE OF SORBITOL BY DIABETICS ACCORDING TO AGE (g/day)

Intakes of sorbitol (g/day)				
Age of consumer (years)	Number of consumers	Median intake	Maximum intake	Number of consumers exceeding 25 g/day
2 to 9	65	0.67	28.32	1
10 to 19	140	0.93	30.15	3
20 to 34	91	0.67	38.61	2
35 to 64	61	0.94	28.42	1
65+	67	5.52	52.86	7

Note: The median intakes are for consumers of the sweetener only.

000365

TABLE 3

DAILY INTAKE OF OTHER BULK SWEETENERS BY DIABETICS ACCORDING TO AGE (g/day)

Bulk sweetener intake (g/day)															
Age of consumer	N	ISOMALT		N	MANNITOL		N	XYLITOL		N	MALTITOL SYRUP		N	LACTITOL	
(years)		median	max.		median	max.		median	max.		median	max.		median	max.
2 to 9	41	0.928	13.829	53	0.055	0.753	17	0.165	0.615	53	0.084	3.364	2	0.750	0.925
10 to 19	67	0.83	7.705	126	0.09	1.55	62	0.308	3.075	126	0.065	7.499	7	0.248	1.418
20 to 34	29	1.04	8.297	77	0.055	1.55	38	0.264	5.535	77	0.03	1.27	4	1.134	2.127
35 to 64	35	2.187	9.832	36	0.09	3.1	10	0.417	6.15	36	0.065	2.55	6	0.319	1.701
65+	46	0.736	8.787	9	0.155	0.64	2	1.234	2.156	9	0.283	3.533	1	0.45	4.074

Note: The median intakes are for consumers of the sweetener only.

N = Number of Consumers

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Continuing Survey of Food Intakes by Individuals (CSFII) and the Diet and Health Knowledge Survey (DHKS), 1989-91 (on CD-ROM)

Department of Agriculture, SS/FCL

Beltsville Human Nutrition Research Center/ARS

March 1996

Ordering Information

Order number PB96-501747INC

$100. Price outside U.S., Canada, & Mexico is $200

To order, call NTIS at (703) 487-4650 for ordering options & handling fee information

Summary:

This CD-ROM contains nationally representative microdata from the 1989-91 Continuing Survey of Food Intakes by Individuals (CSFII) and its follow-up telephone survey the Diet and Health Knowledge Survey (DHKS). The data set includes data on food and nutrient intakes by 15,192 individuals who provided at least one day of dietary data (11,912 individuals provided 3 days of dietary data). The DHKS includes information on dietary knowledge and attitudes from individuals in 5,730 households (mostly main meal planners/preparers) who provided at least one day of dietary data in the CSFII (4,513 DHKS respondents provided 3 days of dietary data). Documentation accompanies the data set which is contained in six record types. The data are accessible through the Statistical Export and Tabulation System (SETS) retrieval software on this CD-ROM. Follow the instructions on the CD-ROM package to install SETS.

WHAT IS SETS?

SETS, the Statistical Export and Tabulation System, provides a means of accessing data from nationwide surveys at the personal computer level using a CD-ROM. The SETS software enables users to manipulate the data according to their analytic needs and to examine individual data records. The SETS User Interface (UI) allows the user to browse survey documentation and files, build record subsets, create tables, and export data to other software systems for analysis.

000402

Additional information:

Format: Datafile-CD-ROM. Contains search and retrieval software. The data file is on one disc. Fully IBM-compatible microcomputer 286 or higher with 640 megabytes of memory; SETS will only operate in a MS-DOS 3.1 or higher environment; Microsoft CD-ROM extensions, version 2.0 or higher; SETS will not work in Macintosh/Apple, or Unix. However, SETS can run on Apple Systems using Soft Windows; SETS will not run on a network. Logoff before initiating SETS applications.

INTRODUCTION

This data set contains information from two surveys conducted by the U.S. Department of Agriculture (USDA). The 1989-91 Continuing Survey of Food Intakes by Individuals (CSFII) includes 1-day food and nutrient intakes by 15,192 individuals of all ages surveyed in the 48 conterminous States and 3-day intakes by 11,912 individuals. The 1989-91 Diet and Health Knowledge Survey (DHKS) includes information on diet, health, and food safety issues from 5,730 individuals identified as main meal planners/preparers in the 1989-91 CSFII.

The surveys were conducted as 3 separate l-year surveys in 1989, 1990, and 1991. The data set includes a set of 3-year weights for use when the data are combined and annual weights for use when only one year of data is used or when each year is analyzed separately.

Please study the complete data set documentation before using the data set. Section 3 provides information about the survey data collection, sample design and weighting, survey response, food coding, and the nutrient data base. Section 4 provides information on simplifying use of the data set. The calculated field documentation in Section 5 describes the process of imputing annual income and the algorithms for calculating fields such as employment status and income as a percentage of the poverty level. Also included here are the lists of foods grouped for table preparation and aggregated for the data set. Section 6 is the glossary and section 7, literature cited.

Section 8 contains the food code manual. This manual contains food codes and descriptions, food code groupings, and coding guidelines. Section 9 contains a streamlined file of food codes and descriptions.

Section 10 contains tabulations of selected fields. The purpose of these "control counts" is to provide users with a way of checking their own input programs and tabulations. Section 11 documents the data set characteristics and format (or layout) of the survey data file. Included are a description of file characteristics and structure as well as counts of records. The file layout describes each data field and references the original question by number so that users may refer to the questionnaires and interviewer's instruction manual. Valid values and their meanings, skip patterns, the position of each field by column, and the number of implied decimal places are given here. A name is provided for each data field that can be used for data processing purposes and facilitates discussion of specific data fields.

Data collection for CSFII began in April 1989 and continued through March 1992. Individuals who took part in the survey were asked to provide 3 consecutive days of dietary data. The first day's data were collected in a personal in-home interview using a 1-day dietary recall. The second and third days' data were collected using a self-administered 2-day dietary record. The DHKS respondents were contacted by telephone, if possible, about 6 weeks following collection of the dietary data and asked to answer a series of questions about knowledge of and attitudes toward diet, health, and food safety issues.

National Analysts (a division of Booz, Allen and Hamilton, Inc.), a private firm in Philadelphia, Pennsylvania, conducted the CSFII/DHKS under contract with the USDA. National Analysts designed the sample; collected the information; edited, coded, and keyed the data; and prepared a final data tape. USDA defined the information to be collected; provided technical information such as food codes, gram weights of common measures of food, and the nutrient composition of foods; and monitored the contract.

The CSFII/DHKS 1989-91 is the most recent of many USDA studies of food consumption. The surveys and their methodologies have been expanded and refined over the years by USDA and cooperating agencies. The surveys are used now, as in the past, to describe food consumption behaviour and to assess the nutritional content of diets for their implications for policies relating to food production and marketing, food safety, food assistance, and nutrition education (1,2). The surveys are a major component of the National Nutrition Monitoring and Related Research Program, a set of related Federal activities intended to provide regular information on the nutritional status of the U.S. population (3,4).

National information on the dietary intakes of individual household members has been collected by USDA since 1965. The first such collection took place as a supplement to the 1965-66 Household Food Consumption Survey; in households sampled in the spring quarter, certain household members were asked to recall their dietary intakes for the day prior to the interview (5). In 1977-78 and in 1987-88, dietary intakes for 3 consecutive days were collected for individuals in households sampled as part of the Nationwide Food Consumption Survey (6,7,8,9). The data were collected using a 1-day recall and a 2-day record. The 1977-78 survey was augmented by five supplemental surveys. These included surveys in Puerto Rico, Hawaii. and Alaska (urban only); a survey of the elderly; and a survey of the low-income population. The 1987-88 survey included a separate sample of low-income households. In addition to the collection of information on dietary intakes, all of the above surveys included the collection of information on food used by households during a 7-day period and the cost of those foods.

In 1985, the USDA initiated the Continuing Survey of Food Intakes by Individuals (CSFII) to provide more frequent information on the dietary status of the population and yearly indications of dietary changes. The first CSFII series (Series I), conducted in 1985 and 1986, included women 19 through 50 years of age and their children 1 through 5 years of age from both general and low-income populations (10, 11). These samples were selected because previous surveys had shown that women of child-bearing age and young children are more likely than other age groups to have diets low in certain nutrients. Individuals who participated in the 1985 and 1986 surveys were asked to provide 6 days of dietary data over a 1-year period. Day 1 data were collected in an in-person interview using a 1-day recall. Subsequent days of data were collected by telephone at approximately 2-month intervals also using a 1-day recall. Also, in 1985, one day of dietary data was obtained from both all-income and low-income samples of men 19 through 50 years of age.

The methodology for CSFII 1989-91 (Series II) included a number of changes from that used in Series I. In Series II, dietary information was collected from all members of sample households for 3 consecutive days rather than from selected household members on 6 non-consecutive days as in CSFII Series I. Also, the inclusion of the DHKS in Series II marks the first time that national information has been collected that links an individual's knowledge and attitudes to his or her dietary behaviour.

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Reference List for Industry Submission, GRN 000076

Pages	*Author*	*Title*	*Publish Date*	*Publisher*	*BIB_Info*
000015 - 000021	Bernt, W.O.; Borzelleca J.F.; Flamm G.; Munro I.C.	Erythritol: A Review of Biological and Toxicological Studies	1996	Regulatory Toxicology and Pharmacology	Volume 24, Number 0098, pgs S191-S197
000026 - 000061	Munro, I.C.; Bernt, W.O.; Borzelleca, J.F.; Flamm, G.; Lynch, B.S.; Kennepohl, E.; Bar, E.A.; Modderman, J.	Erythritol: An Interpretive Summary of Biochemical, Metabolic, Toxicological and Clinical Data	1998	Food and Chemical Toxicology	Volume 36, pgs 1139-1174
000062 - 000067	Joint FAO/WHO Expert Committee on Food Additives	Evaluation of Certain Food Additives and Contaminants	2000	WHO Technical Report Series	Report Series 896, pgs 18-22
000068 - 000097	Joint FAO/WHO Expert Committee on Food Additives	Safety evaluation of certain food additives and contaminants	2000	WHO Food Additives Series	Report Series 44, pgs 15-70
000201 - 000214	Life Sceinces Research Office	Estimation of Exposure to Substances In The Food Supply	July 1988	National Technical Information Service	NA
000215 - 000221	Bernt, W. O.; Borzelleca, J. F.; Flamm, G.; Munro, I. C.	Erythritol: A Review of Biological and Toxicological Studies	1996	Regulatory Toxicology and Pharmacology	Volume 24, pgs S191-S197, Article Number 0098
000224 - 000304	The Institute of European Food Studies	The effect of survey duration on the estimation of food chemical intakes	1998		pgs 1-78
000305 - 000312	FAO/WHO Expert Committee	Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) 1956-1995 (first through forty-fourth meetings)	1996	NA	NA
000313 - 000316	Joint FAO/WHO Expert Committee on Food Additives	Evaluation of Certain Food Additives And Contaminants	2000	NA	WHO Technical Report Series, No . 896
000317 - 000325	Lauer, B. H.; Kirkpatrick, D. C.	Food Additive Intake: Estimated Versus Actual	1991	Monitoring Dietary Intakes	Chapter 15, pgs 170-182

NA- Not applicable

Pages	Author	Title	Publish Date	Publisher	BIB_Info
000326 - 000341	Lowik, M. R. H.	Possible use of food consumption surveys to estimate exposure to additives	1996	Food Additives and Contaminants	Volume 13, Number 4, pgs 427-441
000342 - 000360	Mc Quillan, M.; Heller, E.	Intakes of Intense And Bulk Sweeteners In The UK	1995	British Food Journal	Vol. 97 Iss: 2, pp.10 - 17
000366 - 000401	Munro, I.C.; Bernt, W.O.; Borzelleca, J.F.; Glamm, G.; Lynch, B.S.; Kennepohl, E.; Bar, E.A.; Modderman, J.	Erythritol: An Interpretive Summary of Biochemical, Metabolic, Toxicological and Clinical Data	1998	Food and Chemical Toxicology	Volume 36, pgs 1139 - 1174
000406 - 000413	Virtanen, Suvi M.; Rasanen, Leena; Paganus, Aila; Varo, Pertti; Alkerblom, Hans K.	Intake Of Sugars And Artificial Sweeteners By Adolescent Diabetics	December 1988	Nutrition Reports International	Volume 88, Number 6

NA- Not applicable