



Nga Tran, Dr.PH, MPH
Exponent, Inc.
1150 Connecticut Avenue, NW
Suite 1100
Washington, DC 20036

Re: GRAS Notice No. GRN 000747

Dear Dr. Tran:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000747. We received the notice that you submitted on behalf of PepsiCo, Inc. (PepsiCo) on November 16, 2017, and filed it on December 15, 2017. We received an amendment to the notice on February 20, 2018, clarifying the dates of literature searches.

The subject of the notice is calcium lactate for use in reducing the formation of acrylamide in the manufacturing of potato and vegetable snacks and sweetened crackers at a level of up to 4% in the finished product. The notice informs us of PepsiCo's view that this use of calcium lactate is GRAS through scientific procedures.

PepsiCo provides identity and manufacturing information for calcium lactate. PepsiCo describes calcium lactate (CAS Number 814-80-2) as a white, odorless powder that is water soluble. PepsiCo uses calcium lactate in its pentahydrate form. PepsiCo explains that calcium lactate is synthesized by reacting lime (calcium oxide) with purified L-lactic acid. After the reaction is complete, the solution is spray dried to obtain calcium lactate in powder form. PepsiCo notes that L-lactic acid is produced by fermentation and it meets the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Food Chemicals Codex (FCC 10th edition) specifications, and all other ingredients used in the production of calcium lactate meet the U.S. Pharmacopeia or the FCC specifications.

PepsiCo provides specifications for calcium lactate. The specifications include calcium lactate, 99.0-101.0% w/w; L-isomer, $\geq 98\%$; loss on drying (water of crystallization), 22.0-27.0% w/w; mercury, ≤ 1 mg/kg; arsenic, ≤ 1 mg/kg; and lead, ≤ 0.2 mg/kg. PepsiCo provides analytical data from five non-consecutive batches of calcium lactate to demonstrate that it can be manufactured to meet the specifications for calcium lactate and loss on drying.

PepsiCo estimates the dietary exposure to calcium lactate and calcium from the intended uses and the cumulative exposure to calcium (background plus intended uses) in the U.S. population using the food intake and supplement use data from the National Health and Nutrition Examination Survey (2011-2012 and 2013-2014) and the nutrient composition data from the USDA Food and Nutrient Database for Dietary Studies.

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PepsiCo's estimates are based on the level of calcium lactate in the intended foods (potato and vegetable snacks and sweetened crackers) as 4% and the level of calcium in calcium lactate as 14.5%. The background exposure includes both calcium containing foods and supplements. The mean and 90th percentile dietary exposure to calcium lactate from the intended uses would be 788 and 1,575 mg/day, respectively, which corresponds to calcium exposures of 114 and 228 mg/day, respectively, and lactate intake of 674 and 1,347 mg/day, respectively, for the U.S. population age 1 year and older. The cumulative exposure to calcium would be 1,149 and 1,902 mg/day at the mean and 90th percentile levels, respectively.

PepsiCo discusses data and information relevant to the safety of calcium lactate. PepsiCo notes that FDA has affirmed calcium lactate, relying on the 1978 safety assessment, as GRAS under 21 CFR 184.1207 for several technical effects in food with no limitations other than GMPs. PepsiCo notes that JECFA's acceptable daily intake for lactic acid and all common salts of lactate including calcium, sodium and ammonium, was "not limited," and EFSA, in 2012, expressed no concerns at current use levels based on the endogenous and ubiquitous nature of lactic acid and lactate.

PepsiCo reports that they conducted a comprehensive literature search on the safety of calcium lactate and lactic acid through November 2016 and human health information on calcium through January 2018. PepsiCo summarizes the safety data on calcium intake in humans including the 2011 Institute of Medicine (IOM) report updating the current dietary reference intakes, 2012 EFSA review, and the safety data published subsequent to these reviews. PepsiCo cites the upper limits established by IOM for children 1-8 y (2,500 mg/day), adolescents 9-18 y (3,000 mg/day), adults 19-50 y (2,500 mg/day), and older adults 51+ y (2,000 mg/day), based on calcium excretion in young children and association of excess calcium intake with the formation of kidney stones in older adults. PepsiCo summarizes several recent meta-analyses, systemic reviews, and clinical and observational studies for cardiovascular disease outcomes as well as any other potential adverse outcomes. The results of these studies provide evidence that there is no association between calcium intake and cardiovascular disease. PepsiCo concludes that there is no new evidence that would alter the IOM and EFSA conclusions.

Based on the totality of the data and information described above, PepsiCo concludes that calcium lactate is GRAS for its intended use in food.

Section 301(II) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Section 301(II) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(II)(1)-(4) applies. In our evaluation of PepsiCo's notice concluding that calcium lactate is GRAS under its intended conditions of use, we did not consider whether section 301(II) or any of its exemptions apply to foods containing calcium

lactate. Accordingly, our response should not be construed to be a statement that foods containing calcium lactate, if introduced or delivered for introduction into interstate commerce, would not violate section 301(II).


Conclusions

Based on the information that PepsiCo provided, as well as other information available to FDA, we have no questions at this time regarding PepsiCo's conclusion that calcium lactate is GRAS under its intended conditions of use. This letter is not an affirmation that calcium lactate is GRAS under 21 CFR 170.35 for use in reducing the formation of acrylamide in the manufacturing of potato and vegetable snacks and sweetened crackers at a level of up to 4% in the finished product. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to GRN 000747 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,
**Michael A.
Adams -S**

Dennis M. Keefe, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

 Digitally signed by Michael A.
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