



Eliot Harrison
Lewis and Harrison, LLC
122 C Street, N.W.
Suite 505
Washington, DC 20001

Re: GRAS Notice No. GRN 000786

Dear Mr. Harrison:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000786. We received the notice that you submitted on behalf of Wonderful Citrus, LLC (Wonderful Citrus) on May 31, 2018, and filed it on July 2, 2018. Wonderful Citrus submitted an amendment to the notice on August 21, 2018, in which Wonderful Citrus provides clarifications on information submitted as part of this notice, further explanations on study data in support of safety, a statement on Wonderful Citrus' updated literature search for the subject of this notice and its ionic components, as well as clarifies the intended conditions of use for the subject of this notice.

The subject of the notice is calcium propionate for use as an antibrowning agent in processed fruits at a level of up to 1% of the applied solution. The notice informs us of Wonderful Citrus' view that this use of calcium propionate is GRAS through scientific procedures.

Wonderful Citrus provides identity and composition information for calcium propionate. Calcium propionate is the calcium salt of the three-carbon, straight-chain carboxylic acid, propionic acid. Wonderful Citrus states that the ingredient will be purchased as a known article of commerce manufactured to be food grade, meeting the specifications found in the most recent edition of the Food Chemicals Codex. The ingredient will be used in a blend of calcium salts (chloride, propionate, and ascorbate), dissolved in water, and applied to the surface of processed fruits. Wonderful Citrus suggests that apples and lemons will be the primary fruits to be treated with the solution.

Wonderful Citrus states the ingredient dissociates in water and that exposure would be from the ions derived from the salt. They estimate dietary exposure to these ions by combining data on residuals after application on processed apples and lemons with consumption data from the National Health and Nutrition Examination Survey, through its Food Commodity Intake Database. The estimates of dietary exposure to propionate at the 90th percentile, arrived at by summation of the estimates for apples and lemons individually, are 7.4 mg/day (d) (equivalent to 0.49 mg/kg body weight (bw)/d) and 17.5 mg/d (0.292 mg/kg bw/d) for a child (15 kg) and adult (60 kg), respectively. The

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corresponding estimates for calcium are 2.0 mg/day (0.13 mg/kg bw/d) and 4.8 mg/d (0.080 mg/kg bw/d). Wonderful Citrus discusses background dietary exposure to these ions with information taken from previous GRAS notices and concludes that the estimated dietary exposures from this use of calcium propionate are minor in comparison.

Wonderful Citrus discusses data and information relevant to the safety of calcium propionate. Wonderful Citrus notes that FDA has affirmed calcium propionate, relying on the 1979 safety assessment, as GRAS under 21 CFR 184.1221 when used as an antimicrobial agent in baked goods, cheeses, confections and frosting, gelatins, puddings fillings, jams, and jellies with no limitations other than GMPs.

In support of its safety determination, Wonderful Citrus cites the upper limits (UL) for calcium established by the Institute of Medicine for infants 0 to 6 months (1,000 mg/d), 7 to 12 months (1,500 mg/d), children 1 to 8 years (2,500 mg/d), children 9 to 13 years and adolescents 14 to 18 years (3,000 mg/d), adults 19 to 50 years (2,500 mg/d), and older adults 51 years and older (2,000 mg/d) based on calcium excretion in infants and association of excess calcium intake with the formation of kidney stones in older adults. Wonderful Citrus notes that the European Commission's Scientific Committee on Food established a UL of 2,500 mg calcium/d for all age groups. Wonderful Citrus also notes that the Joint FAO/WHO Expert Committee on Food Additives' acceptable daily intake for propionic acid and its calcium, potassium and sodium salts was "not limited." Wonderful Citrus reports that they conducted a comprehensive literature search on the safety of calcium propionate and its ionic components through September 2017 and that no adverse effects relevant to humans were reported in animal studies.

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

Potential Labeling Issues

Under section 403(k) of the Federal Food, Drug, and Cosmetic (FD&C Act), a food is misbranded if it contains any chemical preservative, unless the label states that fact. Under section 403(i)(2) of the FD&C Act, a food is misbranded unless its label bears the common or usual name of each ingredient. Further, under section 403(a) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any way. Wonderful Citrus' intended use of calcium propionate constitutes use as a preservative. Therefore, the ingredient statement on labels of food products containing calcium propionate must comply with the labeling regulations implemented in sections 403(k) and 403(i)(2) of the FD&C Act. For example, 21 CFR 101.22(j) requires that the label of a food with an added chemical preservative must declare both the common or usual name of the ingredient and a separate description of its function. Further, food that is subjected to any form of preservation, except as provided in 21 CFR 101.95(c), may not be labeled as "fresh." Questions related to food labeling should be directed to the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition.

Section 301(II) of the 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 Wonderful Citrus' notice concluding that calcium propionate 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 propionate. Accordingly, our response should not be construed to be a statement that foods containing calcium propionate, if introduced or delivered for introduction into interstate commerce, would not violate section 301(II).


Conclusions

Based on the information that Wonderful Citrus provided, as well as other information available to FDA, we have no questions at this time regarding Wonderful Citrus' conclusion that calcium propionate is GRAS under its intended conditions of use. This letter is not an affirmation that calcium propionate is GRAS under 21 CFR 170.35 for use as an antibrowning agent in processed fruits at a level of up to 1% of the applied solution. 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 000785 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.
Adams -S
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