



Martin J. Hahn
Hogan Lovells US LLP
Colombia Square
555 Thirteenth Street, NW
Washington, DC 20004

Re: GRAS Notice No. GRN 000806

Dear Mr. Hahn:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000806. We received the notice on August 6, 2018, and filed it on September 18, 2018. On December 11, 2018 and February 14, 2019, we received amendments that included additional information about the intended uses, methodology used to determine the composition of dolomite, additional description of toxicological studies, and dietary exposure.

The subject of the notice is dolomite for use as a substitute for calcium and magnesium salts added to to enhance the taste of purified water, at a maximum level 184 mg/L corresponding to 40 mg/L calcium ions and 25 mg/L magnesium ions. The notice informs us of Hogan Lovells' view that this use of dolomite is GRAS through scientific procedures.

Our use of the term "dolomite" in this letter is not our recommendation of that term as an appropriate common or usual name for declaring the substance in accordance with FDA's labeling requirements. Under 21 CFR 101.4, each ingredient must be declared by its common or usual name. In addition, 21 CFR 102.5 outlines general principles to use when establishing common or usual names for non-standardized foods.¹ Issues associated with labeling and the common or usual name of a food ingredient are under the purview of the Office of Nutrition and Food Labeling (ONFL) in the Center for Food Safety and Applied Nutrition. The Office of Food Additive Safety did not consult with ONFL regarding the appropriate common or usual name for dolomite.

Hogan Lovells discusses the identity of dolomite (CAS Reg. No. 16389-88-1) and states that on a mass percentage basis, dolomite typically contains 21% calcium (30% calcium oxide) and 12% magnesium (21% magnesium oxide). Hogan Lovells states that the empirical formula of dolomite is $\text{CaMg}(\text{CO}_3)_2$ and the molecular weight is 184.39. Trace levels (<0.1%) of other elements such as iron, sodium, phosphorous and sulfur are present in dolomite. Hogan Lovells describes the appearance of dolomite as a white or

¹ If dolomite is added to a food which has a standard of identity, such as any of the types of bottled water in 21 CFR 165.110, we would expect the water ingredient of the beverage to meet provisions in the standard of identity and the statement of identity for the multi-ingredient beverage to reflect the addition of dolomite.

U.S. Food and Drug Administration
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grey to brownish material in crushed and granular form. Hogan and Lovells states that the density of dolomite is 2.2 to 2.9 g/cm² at 20 °C and the solubility in water is 0.032 g/L at 10 °C.

Hogan Lovells describes the method of manufacture of dolomite. Dolomite is mined from deposits that are shown to be free of heavy metals. Dolomite is crushed to meet the proper size, screened, and then dried. The dolomite is tested to ensure that it complies with the specifications for heavy metals and is then packaged and stored under dry ambient conditions. Hogan Lovells states that dolomite is prepared under current good manufacturing practices using materials of suitable purity and quality for their intended use.

Hogan Lovells provides specifications for dolomite which include limits for CaO (≥30%), MgO (≥21%), and heavy metals including lead (<1 mg/kg), cadmium (<2 mg/kg), and arsenic (<1 mg/kg) among others. Hogan Lovells states that the identity of the mined product is verified in accordance with the European Standard NF EN 16003 (Chemicals used for treatment of water intended for human consumption- calcium magnesium carbonate). Hogan Lovells provides results of batch analyses to demonstrate that the mined dolomite can be manufactured to meet specifications. Hogan Lovells also states that manufacturers of bottled water must meet the standards for microbiological quality under 21 CFR 165.110.

Hogan Lovells states that prior to its use, dolomite is loaded onto a filter and treated with hot water (>85 °C) for 30-60 minutes. After cooling, the dolomite in the filter is used to re-mineralize carbonated (pH 4-6) or non-carbonated water that has been purified by reverse osmosis or distillation. Hogan Lovells states that remineralization occurs at ambient temperature and is controlled by flow rate and the typical contact time is 15-30 minutes. Dolomite-infused water is then filtered to remove fine particles and treated by thermal processing, UV light, or ozone in accordance with current good manufacturing practices and the bottled water standards (21 CFR 165.110). Hogan Lovells describes results of two pilot studies evaluating the composition of the purified water remineralized with dolomite, targeting 20 mg/L Ca and 12.2 mg/L Mg in the first study and 112 mg/L Ca and 68 mg/L Mg in the second study. Hogan Lovells states the dolomite used in these pilot studies met their specifications and that the levels of heavy metals in the resultant mineralized water were below the limits of detection.

Dolomite is intended for use as a substitute for calcium and magnesium salts presently used added to purified water. Dolomite dissolves readily in water to the same individual ions (i.e., calcium, magnesium, bicarbonate) as other common salts such as calcium carbonate and magnesium carbonate. The chemical reaction which occurs is as follows:
$$\text{CaMg}(\text{CO}_3)_2 + 2 \text{CO}_2 + 2 \text{H}_2\text{O} \rightarrow \text{Ca}^{2+} + \text{Mg}^{2+} + 4 \text{HCO}_3^{-.2}$$

Hogan Lovells presents exposure estimates for bottled water in the U.S. and estimates exposure to calcium and magnesium from this use of dolomite in bottled water. Hogan

² Calcium carbonate is affirmed as GRAS in accordance with 21 CFR 184.1191. Magnesium carbonate is affirmed as GRAS in accordance with 21 CFR 184.1425.

Lovells estimates the average and 90th percentile intake for bottled water, obtained using NHANES 2013-2014 survey data for consumers of bottled water (consumers only). Hogan Lovells calculates mean and 90th percentile exposures to calcium and magnesium for all ages from this use of dolomite at the maximum use level (184 mg/L dolomite) in bottled water³: mean 33.7 mg per person per day (p/d) and 90th 71 mg/p/d for calcium, and mean 21 mg/p/d and 90th 44 mg/p/d for magnesium.

Hogan Lovells states that the intended use of dolomite is supported by the safety reviews of calcium and magnesium, components of dolomite, completed by the Select Committee on GRAS Substances (1975), the European Commission Scientific Committee on Food (2001 and 2003), the Institute of Medicine (1997 and 2011), and the European Safety Authority (2016).

Hogan Lovells discusses published studies and other safety data and information on dolomite and its components to support the safety of dolomite. In a published 90-day study, no effects were reported at 1,280 mg dolomite/kg body weight (bw)/d in rats. In another published study in rats, administration of dolomite during gestation produced no adverse maternal and embryo-fetal toxicity at 1,500 mg/kg bw/d, the highest dose tested. In an unpublished 42-day piglet study, 2,430 mg/kg bw/d of MDMM (mixture of dolomite, magnesite, and magnesium-phyllsilicates) produced no toxic effects. In unpublished bacterial reverse mutation assays and *in vitro* chromosome aberration test in human lymphocytes, MDMM was found to be non-mutagenic and did not cause chromosome aberrations. In an unpublished *in vivo* mouse micronucleus test, no toxicity to the bone marrow was seen at 2,000 mg/kg bw/d.

Hogan Lovells states that the safety studies show that dolomite is a safe source of calcium carbonate and magnesium carbonate and that dolomite is safe for oral consumption at a level of 353.3 mg/p/d (or 5.89 mg/kg bw/d) in humans.

Based on the totality of data and information available, Hogan Lovells concludes that the intended use of dolomite is GRAS.

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 Hogan Lovells' notice concluding that dolomite 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 dolomite. Accordingly, our response should not be construed to be a statement that foods containing dolomite, if introduced or delivered for introduction into interstate commerce, would not violate

³ Hogan Lovells estimates mean and 90th percentile bottled water intakes for all ages to be 841 and 1,775 g/p/d.

section 301(ll).

Conclusions

Based on the information that Hogan Lovells provided, as well as other information available to FDA, we have no questions at this time regarding Hogan Lovells' conclusion that dolomite is GRAS under its intended conditions of use. This letter is not an affirmation that dolomite is GRAS under 21 CFR 170.35. 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 000806 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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