



Gary L. Yingling
Morgan, Lewis and Bockius, LLP
1111 Pennsylvania Ave, NW
Washington, DC 20004

Re: GRAS Notice No. GRN 000753

Dear Mr. Yingling:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000753. We received the notice that you submitted on behalf of Taradon Laboratory (Taradon) on December 21, 2017 and filed it on January 24, 2018. On June 1, 2018, and June 13, 2018, we received amendments containing additional information about the data used to support safety.

The subject of the notice is sodium thiocyanate for use as a component of a lactoperoxidase system used as an antimicrobial in milk for the production of fresh cheese (including mozzarella and cottage cheeses), frozen dairy desserts, fermented milk, flavored milk drinks, and yogurt. Taradon states that sodium thiocyanate will constitute 5% (w/w) of the lactoperoxidase system that is added at up to 300 mg/L of milk. The notice informs us of Taradon's view that these uses of sodium thiocyanate are GRAS through scientific procedures.

Taradon states that the CAS registry number for sodium thiocyanate is 540-72-7. Taradon describes sodium thiocyanate as white free-flowing crystals that are readily soluble in water.

Taradon states that it will not manufacture sodium thiocyanate but rather will source sodium thiocyanate with food-grade specifications for use in the manufacture of the lactoperoxidase system. Taradon states that sodium thiocyanate is manufactured under current good manufacturing practice using common food industry materials and processes. Taradon provides acceptance criteria for sodium thiocyanate; these include appearance, solubility, purity ($\geq 98\%$), moisture ($\leq 2\%$), pH of 1% solution (6.0-8.0), iron ($< 0.0002\%$), chloride ($\leq 0.04\%$), lead ($\leq 0.001\%$), and sulfate ($\leq 0.04\%$).

Taradon reports that the sodium thiocyanate in the lactoperoxidase system is consumed and no exogenous sodium thiocyanate is expected in the finished food. However, Taradon estimates dietary exposure to sodium thiocyanate using consumption data from National Health and Nutrition Examination Surveys (NHANES), 2009-2012, and background intake from food. Taradon estimates users-only dietary exposure to sodium thiocyanate for the U.S. population (above the age of 2) at 2.4 mg/person/day (d) and 7.2 mg/person/d at the mean and 90th percentile, respectively. On a body weight basis,

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these estimates are 0.04 g/kg bodyweight (bw)/d at the mean, and 0.12 g/kg bw/d at the 90th percentile.

Taradon states that thiocyanate¹ is naturally present in cow's milk. Taradon uses publicly available information as evidence that thiocyanate is a component of human physiology, due to its presence in saliva and gastric juice, and in other foods consumed by the general population. Taradon discusses publicly available information on the absorption, distribution, excretion, and metabolism of sodium thiocyanate, concluding that majority of the orally ingested thiocyanate is excreted unchanged, with small amounts metabolized.

Taradon cites and discusses a published 2-year chronic toxicity/carcinogenicity bioassay on thiocyanate, which concluded that the treatment of rats with 3.2 g/L in drinking water did not result in obvious adverse effects. Taradon discusses published studies to conclude that the levels of thiocyanate associated with toxicity, including goitrogenic effects, are well above levels expected from the intended use. Taradon provides published and unpublished information (including a FAO/WHO technical meeting report) on the safety of thiocyanate use in the context of the safety of milk treated with lactoperoxidase system.

From the totality of data and information available, Taradon concludes that the intended use of sodium thiocyanate is generally recognized as safe.

Standards of Identity

In the notice, Taradon states its intention to use sodium thiocyanate as part of the lactoperoxidase system in several food categories, including foods for which standards of identity exist, located in Title 21 of the CFR. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

¹ In the notice, the notifier uses sodium thiocyanate and thiocyanate interchangeably when describing sodium thiocyanate. FDA notes that whereas the article of commerce for the notice is sodium thiocyanate, the active component of the lactoperoxidase system, as well as the chemical form present in foods and human physiology is thiocyanate.

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 Taradon's notice concluding that sodium thiocyanate 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 sodium thiocyanate. Accordingly, our response should not be construed to be a statement that foods containing sodium thiocyanate, if introduced or delivered for introduction into interstate commerce, would not violate section 301(II).

Conclusions

Based on the information that Taradon provided, as well as other information available to FDA, we have no questions at this time regarding Taradon's conclusion that sodium thiocyanate is GRAS under its intended conditions of use. This letter is not an affirmation that sodium thiocyanate 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 000753 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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