U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

William J. Rowe
GRAS Associates, LLC
11810 Grand Park Ave, Suite 500
North Bethesda, MD 20852

Re: GRAS Notice No. GRN 001155

Dear Mr. Rowe:

The Food and Drug Administration (FDA, we) completed our evaluation of the supplement that you submitted on behalf of Fresh Inset S.A. (Fresh Inset) to GRN 001155. We received the supplement on March 21, 2025. The supplement addresses increased use levels and additional uses for the subject of GRN 001155. Fresh Inset submitted information on September 10, and November 21, 2025, clarifying aspects of the narrative and the intended use, respectively.

We previously responded to GRN 001155 on April 23, 2024. We stated that we had no questions at that time regarding Fresh Inset's conclusion that 1-methylcyclopropene and α-cyclodextrin complex (1-MCP complex) is GRAS for use as an ethylene inhibitor on stickers placed inside food packaging for cut fresh produce (sliced melon, pineapple, apple, mushroom, and shredded cabbage/coleslaw) at a maximum level of 9.086 µg of 1-MCP per kg of fresh produce to extend the shelf life of the fresh produce.[1]

In the supplement dated March 20, 2025, Fresh Inset informs us of its view that 1-MCP complex is GRAS, through scientific procedures, for use as an ethylene inhibitor on stickers placed inside food packaging for cut fresh produce or applied directly to the inside of packaging containing the produce up to a maximum level of 1-MCP per kg of produce specified in Table 1 to extend the shelf life of the fresh produce.[1,2]

[1] Fresh Inset stated that 1-MCP complex is not intended for use in any products under the jurisdiction of the U.S. Department of Agriculture or in infant formula.
[2] Fresh Inset stated that this supplement to GRN 001155 is for 1-MCP complex coated on a 4 cm^2 sticker; whereas in the original GRN 001155, the sticker was 1 cm^2.

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Table 1. Intended food uses for 1-MCP complex.

Produce	Maximum use level (µg 1-MCP/kg produce)
Fruits (kiwi, dragon fruit, pomegranate, apricot, cherry, fig, plum, strawberries, grapes, pears)	51.29
Leafy greens (beet greens, chard, collards, cress, dandelion greens, kale, mustard greens, watercress, spinach)	139.21
Lettuce (cabbage, romaine, radicchio, Boston, arugula, mixed, salad packs including salads with other ingredients like egg and cheese)	161.19
Other vegetables (snow peas, green peas, cucumber, celery, broccoli, cauliflower, brussels sprouts, sprouts, onions (including leek and green onion), string beans, peppers, eggplant, asparagus, squash, Bok choy, jicama, parsnips, beets, shallot, radish)	30.24
Berries (blueberries, blackberries, raspberries), tomatoes, ginger, herbs	31.10
Carrots	35.82
Sliced melon/mushroom[a]	36.344
Pineapple rings or chunks[a]	29.092
Sliced apple[a]	16.5
Shredded cabbage coleslaw[a]	33
[a] Use in these foods was previously described in GRN 001155 at a maximum level of 9.086 µg 1-MCP/kg produce.	

Fresh Inset states that the manufacturing method and specifications will remain the same as previously described in GRN 001155 and provides an updated dietary exposure estimate to 1-MCP based on the intended uses of 1-MCP complex using food consumption data from the 2017-2020 National Health Nutrition Examination Survey (NHANES). Fresh Inset estimates the mean and 90th percentile eaters-only dietary exposure to 1-MCP for the U.S. population aged 2 years and older to be 6.41 µg/person(p)/d (0.102 µg/kg body weight (bw)/d) and 14.36 µg/p/d (0.229 µg/kg bw/d), respectively. Fresh Inset notes that the intended uses of 1-MCP complex are substitutional for other uses of 1-MCP, as stated in GRN 000585,[3] except for the potential additional dietary exposure to 1-MCP from post-harvest application. Based on the highest post-harvest use level of 1-MCP indicated for apples (0.004 mg/kg) and the assumption that 2 kg of 1-MCP-treated produced is consumed daily, Fresh Inset estimates the highest 90th percentile eaters-only cumulative dietary exposure to 1-MCP, including background sources, to be 23.3 µg/p/d for adult females.

Fresh Inset relies on safety information discussed in GRN 001155 to support the intended uses in this supplement. Fresh Inset states that based on an updated literature search through March 2025, there are no new publications that would contradict their GRAS conclusion.

[3] The subject of GRN 000585 is 1-MCP complex. We evaluated this notice and responded in a letter dated January 29, 2016, stating that we had no questions at that time regarding the notifier's GRAS conclusion.

Based on the available data and information, Fresh Inset concludes that 1-MCP complex is GRAS under the intended conditions of use.

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

Section 301(ll) 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(ll)(1)-(4) applies. In our evaluation of Fresh Inset's supplement concluding that 1-MCP complex is GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing 1-MCP complex. Accordingly, our response should not be construed to be a statement that foods containing 1-MCP complex, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Fresh Inset provided, as well as other information available to FDA, we have no questions at this time regarding Fresh Inset's conclusion that 1-MCP complex is GRAS under its intended conditions of use. This letter is not an affirmation that 1-MCP complex 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 the supplement to GRN 001155 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
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Director
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