



Riëtte L. van Laack, Ph.D.
Hyman, Phelps & McNamara, P.C.
700 Thirteenth St. NW, Suite 1200
Washington, DC 20005

Re: GRAS Notice No. GRN 000885

Dear Dr. van Laack:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000885. We received the notice that you submitted on behalf of Wacker Chemie AG (Wacker) on October 10, 2019, and filed it on December 2, 2019. Wacker submitted an amendment to the notice on February 12, 2020, that provided additional details on the manufacturing process and dietary exposure.

The subject of the notice is vinyl acetate-vinyl laurate copolymers (VAVLP) with 5-40% (w/w) vinyl laurate (VL) for use as a component of chewing gum base at a level of up to 26% by weight to reduce or eliminate the use of additional softeners. The notice informs us of Wacker's view that this use of VAVLP is GRAS through scientific procedures.

Our use of the term, "VAVLP," 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 nonstandardized foods. 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 "VAVLP."

Wacker provides information about the identity and composition of VAVLP. Wacker states that the chemical name is "dodecanoic acid, ethenyl ester, polymer with ethenyl acetate" (CAS Number: 26354-30-3). VAVLP is a white to pale-yellowish, odorless, tasteless solid that is insoluble in water and has a molecular weight of >70,000 g/mol. Wacker states that the present notice was submitted in part to expand the identity of VAVLP (20 and 40% VL), the subject of GRN 000606¹, to include copolymers with 5-40% (w/w) VL.

¹ VAVLP (20 and 40 % VL) was the subject of GRN 000606. We evaluated this notice and responded in a letter dated May 27, 2016 stating that we had no questions at that time regarding the notifier's GRAS conclusion.

Wacker states that the manufacturing process of VAVLP is the same as in GRN 000606, but that the process has been optimized to decrease the VL monomer content. VAVLP is produced by the chain-growth polymerization of vinyl acetate (VA) with VL of high purity (>99.8% and 98%, respectively). Tert-butylperoxy-2-ethylhexanoate (TBPEH) and 2,2-di(tert-butylperoxy) butane (DBPB) are used as radical initiators to induce polymerization, and either acetaldehyde or isopropanol are used as the chain transfer agent during the polymerization process. After polymerization, the polymer is purified by evaporation at an elevated temperature under vacuum and by steam stripping to remove any remaining chain transfer agent, unreacted monomers, and decomposition products of the radical initiators.

Wacker provides specifications for VAVLP that include: the percentage VL (5-40% w/w), viscosity (3-13 mPas), free acetic acid ($\leq 0.05\%$), free saponification number (475-630 mg potassium hydroxide/g), residual VA monomer (≤ 5 mg/kg), residual VL monomer (≤ 1000 mg/kg), and isopropanol (≤ 50 mg/kg). Wacker also indicates that, based on their calculations, the maximum limit for the radical initiators (TBPEH and DBPB) would be ≤ 0.1 mg/kg. Wacker states that the specifications do not include limits for heavy metals, as routine analyses demonstrate that their levels are below the limit of detection of 1 mg/kg. Wacker provides results from the analysis of five non-consecutive batches of VAVLP to demonstrate that it can be produced to meet their stated specifications.

Wacker provides a user-only exposure estimate for chewing gum of 2.9 g/person (p)/day (d) at the mean and 6.0 g/p/d at the 90th percentile for the U.S. population aged 2 years or older using food consumption data from the combined 2011-2014 National Health and Nutrition Examination Survey. Wacker indicated that the maximum technically feasible use level of VAVLP is 17% by weight in the chewing gum. At this level, the exposure to VAVLP for the U.S. population aged 2 years or older is 491 mg/p/d at the mean and 1015 mg/p/d at the 90th percentile. Wacker also addresses the exposure to potential impurities (acetic acid, VA monomer, VL monomer, isopropanol, and radical initiators) from the intended use of VAVLP. Wacker states that they expect these impurities and their breakdown products to be removed during processing of VAVLP. Wacker notes that this use of VAVLP is substitutional for that in GRN 000606. Therefore, Wacker concludes that there would be no increase in dietary exposure to VAVLP from that in GRN 000606.

Wacker incorporates all data and information from GRN 000606 that is pertinent to the safety evaluation of VAVLP. Wacker also discusses published safety studies on isopropanol for the intended use as a manufacturing aid. Furthermore, Wacker discusses unpublished toxicological studies, studies in humans, as well as safety evaluations by several international bodies, including the Organisation for Economic Co-operation and Development and European Food Safety Authority, to corroborate the safety of isopropanol. Wacker also states that the estimated exposure to residual isopropanol present in VAVLP based on the estimated exposure of VAVLP and isopropanol specifications is below levels of toxicological concern. Based on these evaluations, Wacker concludes that the use of isopropanol as a chain transfer agent is

safe. Finally, Wacker states that no new safety information since GRN 000606 for VL or VAVLP was found in the updated literature search through August 2019.

Thus, based on the totality of the data and information described above, Wacker concludes that VAVLP is GRAS for its intended uses in food.

Wacker includes the statement of a panel of individuals (Wacker's GRAS panel). Based on its review, Wacker's GRAS panel concluded that VAVLP is safe under the conditions of its intended 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 Wacker's notice concluding that VAVLP 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 VAVLP. Accordingly, our response should not be construed to be a statement that foods containing VAVLP, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Wacker provided, as well as other information available to FDA, we have no questions at this time regarding Wacker's conclusion that VAVLP is GRAS under its intended conditions of use. This letter is not an affirmation that VAVLP 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 000885 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Susan Carlson, Ph.D.
Director

Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

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