



June 15, 2018

Mike Sung, Ph.D  
Sanford Process Inc/Precision Coating  
1 Shorr Court  
Woonsocket, RI 02895

Re: Pre-Notification Consultation (PNC) 002127

Dear Dr. Sung:

This is in response to your e-mail dated April 19, 2018 requesting FDA's opinion of the suitability for food contact use of sealed anodized aluminum (hard anodic coating; product name Hardcoat). We have reviewed the information you provided on the manufacture of the hard anodic coating in e-mails dated November 27, 2017 and February 9, 2018.

The hard anodic coating is anodized aluminum that is sealed using a process, termed the Micalox process. The finished surface of the hard anodic coating consists primarily of aluminum hydroxide and aluminum oxide with minor levels of aluminum fluoride and nickel hydroxide. The hard anodic coating will serve as the food contact surface of parts of repeat use food processing equipment such as molding equipment and extruders. The intended technical effect of the hard anodic coating is to serve as a durable, abrasion resistant surface.

Repeat use parts such as these will ordinarily contact a large amount of food over their lifetime resulting in very low dietary concentrations of any impurities initially present in the hard anodic coating that are available for migration to food. The conditions of use (*e.g.*, pH, temperature, impact forces) of the hard anodic coating will be limited to those in which it is expected to remain insoluble and resistant to corrosion, abrasion, and chemical attack, such that there is little or no likelihood that components of the material will migrate to food above insignificant amounts, nor would the material otherwise affect food. Based on this information, we are not aware of any known or likely safety issues associated with the intended use of the hard anodic coating described in your inquiry.

Therefore, under the conditions described above, we consider the hard anodic coating acceptable for the intended use and it does not require premarket approval as a food additive under section 409 of the Federal Food, Drug and Cosmetic Act (*i.e.*, the submission of a food contact notification, a food additive petition, or a threshold of regulation exemption request is not required).

Please do not hesitate to contact us if you have any further questions.

Sincerely,

**U.S. Food and Drug Administration**  
**Center for Food Safety & Applied Nutrition**  
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College Park, MD 20740  
[www.fda.gov](http://www.fda.gov)

Kenneth McAdams  
Consumer Safety Officer  
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cc: PNC 2127