



December 1, 2021

Alexandra Veit  
KYOCERA Fineceramics Precision GmbH  
Lorenz-Hutschenreuther-Str. 81  
95100 Selb, Germany

Re: Use of Certain Types of Ceramic Materials in Contact with Food

Dear Ms. Veit:

This is in reply to your e-mail inquiry dated November 8, 2021, asking for FDA's opinion on the food-contact use of certain types of ceramic materials as follows: aluminum oxide, silicon nitride, and zirconium oxide with yttrium oxide. Please be aware that FDA does not offer opinions on specific products; the Agency only offers opinions on the use of classes of materials for use in contact with food.

The ceramics are to be used as durable, abrasion and corrosion resistant surfaces for repeated-use parts of food processing equipment, e.g., seal faces, bearings, pump pistons, nozzles.

Under the conditions that: 1) the surfaces composed of these materials in repeated-use parts of food processing equipment will contact a large amount of food over their lifetimes and 2) the conditions of use (e.g., moisture, temperature, pH) of the parts will be limited to those in which they are expected to be remain stable, insoluble, chemically inert, and resistant to corrosion and abrasion, we expect there is little or no likelihood that constituents of these materials would be transferred to food at other than insignificant amounts, nor would the materials otherwise affect food. Historically, FDA has issued favorable opinions on the use of such materials in contact with food (assuming insignificant migration to food), and we are currently not aware of any known or likely safety issues associated with the intended use of these materials. Therefore, under the conditions described above, we consider the above materials acceptable for the intended use described and do not require premarket approval as food additives 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).

Furthermore, please be aware that the finished materials must be of a suitable purity for the intended use in contact with food, and the general safety requirements of the United States Federal Food, Drug and Cosmetic Act must be met for the use of materials in contact with food, including that the materials must not impart substances to food that may render the food injurious to health, nor impart any taste, odor or color to food that would render the food unfit for consumption.

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

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

Sincerely,

Kenneth McAdams  
Consumer Safety Officer  
Division of Food Contact Notifications, HFS-275  
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Center for Food Safety and Applied Nutrition