



OCT 30 1995

Ms. Sheryl A. Montanari  
The Carborundum Company  
Structural Ceramics Division  
P.O. Box 1054  
Niagara Falls, New York 14302-1054

Dear Ms. Montanari:

This is in response to your letter, dated September 7, 1995, in which you request that we approve the use of a controlled porosity sintered silicon carbide for use in fluid food handling equipment, particularly in mechanical seals and bearings. The information you provided states that the chemical composition of controlled porosity silicon carbide is identical to conventional silicon carbide sintered material, except for the pores which are voids in the material. You specifically request that we consider that the use of porous silicon carbide is not a food additive situation.

FDA does not approve specific products for use in contact with food. Instead, the agency authorizes, through the issuance of food additive regulations, the use of specific chemicals in the production of food-contact articles. In addition, the agency has established, as published in the *Federal Register* of July 17, 1995 (60 FR 36581), a "Threshold of Regulation" policy, which is a process for determining when the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial as not to require regulation of the substance as a food additive.

We have reviewed the information you provided on the chemical analysis and properties of sintered porous silicon carbide and we conclude that, like non-porous sintered silicon carbide, the use of this material under repeat use conditions in fluid handling components, primarily as mechanical seals and bearings, is highly durable and resistant to corrosion and heat. We also conclude that there is little or no

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likelihood of significant migration of this material into food when used as described above, and that these uses of sintered porous silicon carbide would not require a food additive regulation.

We trust that this responds satisfactorily to your inquiry. If you have any further questions, please do not hesitate to contact us.

Sincerely yours,

*Corbin I. Miles*

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