

Ralph Purcell - CC-DTM-3

October 24, 1989

Bill Johnson
Waterloo, Ontario, Canada

SUBJECT: GEONS ^{19/and 198} - FDA STATUS

Geons ^{19/and 198 are} ~~is a~~ homopolymer polyvinyl chloride (PVC) resins. Polyvinyl chloride is prior sanctioned for use in general food contact applications, both flexible and rigid. The prior sanction is based on an article by A. J. Lehman, from the FDA, published in the Journal of the Association of Food and Drug Officials, July, 1951. The current Good Manufacturing Practice (GMP) specifications for prior sanctioned PVC are a maximum volatility of 3.0% (1 hour at 105°C) and an inherent viscosity of not less than 0.35 by ASTM D-1243-79. ~~Geons ^{19/and 198} meets the GMP~~ ^{providing} ~~and therefore meets the~~ ^{they} current requirements of the FDA for general food contact applications.

PVC is also listed as an acceptable ingredient of food contact articles under 21CFR:

175.105	177.1200
175.300	177.2250
176.180	179.45
177.1010	

If you have any further questions, please call me at 216/374-3422.

W. E. Bachtel

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21CFR Sections 300 to 400 cover drugs. There is no section 477. Sections 461-499 are reserved for future use (see attached).

W. E. Bachtel

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