AN 4446

September 7, 1990

Jong Kim
ALTC

SUBJECT: NIGROSINE AS A POLY COATING FOR PVC

The nigrosines do not have FDA clearance for use as an adjunct in PVC food contact articles. However, those substances used in the polymerization process to produce an acceptable polymer need not have specific FDA clearances, so long as Good Manufacturing Practice (GMP) is used. GMP assures that those substances used in the polymerization of a polymer do not adulterate food; i.e., are not reasonably expected to migrate into food. Industry practice is to consider "no migration" to be no detectable migration of a substance by an analytical method sensitive to 50 ppb in somewhat exaggerated extraction studies performed to simulate the intended end use conditions. For biologically reactive substances, such as carcinogens, heavy metals, economic poisons and substances with an LD50 of less than 40 mg/kg, a detection limit of 10 ppb is used. Alternately, if one knows the concentration of the substance in question in the end food contact article, one can assume a worst case situation and by calculation, determine if a potential migration problem would exist.

A 50 ppb detection limit would be appropriate for the nigrosines based on the available information. One word of caution, if a detection limit is set below 50 ppb and detectable migration is seen, no matter how low, a food additive would exist.

If you already know the expected concentration of nigrosine in PVC made with it as a polycoating, we can make some assumptions and calculate a worst case situation. Otherwise, if you wish to perform appropriate extraction studies, I will be glad to help you design them.

If you have any other questions, please call me on Ext. 3422.

W.C. Bachtel/jp

W. C. Bachtel

0907-2/jp

20877001

BFG07659