

GEON FDA AUDIT/86416 trans 0027

May 26, 1993

Audit findings: A review of the present recipe indicates that this compound meets the current requirements of the FDA for general use in contact with foods of high water content only. It also meets the requirements for use in contact with all types of foods when used in accordance with 21CFR 175.105, 21CFR 175.300, and 177.1210. The final food contact article must meet the extractive requirements of these sections and 21CFR 178.3790.

Note: PVC may not be used to package alcoholic beverage until such time as the Alcohol, Tobacco and Firearms Bureau of the Treasury Department approves this use.

No prior assessment of the FDA status of this product was found in the HT&PS files.

Assessment and recommendations: The Geon technical data sheet indicates that this compound is FDA acceptable and medical grade. The technical data sheet should be modified to include the specific limitations and requirements regarding the FDA clearance of this compound as described above. Since this compound would be acceptable for a variety of indirect food contact applications, there is a good chance that it would be allowed to be used in some medical applications. However, there is no guarantee that a medical device made from this product will be acceptable to FDA. One option to insure proper communication would be to describe this product as "medical grade" with a footnote defining the term and providing a caveat such as "Made from ingredients which are acceptable under current FDA requirements for direct or indirect food contact applications. This information is supportive of efforts to gain acceptance of a medical device containing this product but is not intended to denote any approval on the part of FDA for any medical device application."

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GEON FDA AUDIT/86447 TRANS 003

May 24, 1993

Audit findings: A review of the current recipe indicates that this compound does not have any clearance for indirect food additive applications under the current requirements of the FDA.

No prior assessment of the FDA status of this product was found in the HT&PS files.

Assessment and recommendations: The Geon CIM Vinyl technical bulletin does not make any statements regarding the FDA status of this product. Therefore no changes are needed.

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