

September 16, 1993

To: Jim Gray

Subject: Geon 8857 White 126 FDA Status

In response to your request I am providing information on the FDA status of Geon 8857 White 126 and its ingredients.

As I have previously noted, tubing that feeds potable water to an ice maker in a refrigerator falls under the FDA "housewares exemption". Although this application is not specifically regulated by law, suppliers such as Geon frequently rely on NSF for third party certification.

One of the factors that NSF considers in assessing the acceptability of a product is the FDA status of the component(s). Assuming that there are no new toxicity issues, products have a better chance of being certified if they and/or their raw materials have FDA clearance. Generally, those with the broadest clearance have that best chance. Any compound which would be acceptable for bottled water which is regulated by FDA would be acceptable for applications such as an ice maker feed tube. Products containing compounds which do not have any FDA clearances will necessitate a more indepth assessment, particularly those that where one or more raw materials do not have any FDA clearance and where there are toxicological concerns.

A review of the recipe for Geon 8857 White 126 indicates that it does not have any FDA clearance. All of the ingredients except Drapex 409, Mark 4716, and the red pigment, No. 9303 Erythrosine Lake Concentrate have clearance under one or more of the direct or indirect food additive sections in Chapter 21 of the Code of Federal Regulations.

Because of unresolved questions about the safety of the above ingredients which do not have FDA clearance, we cannot recommend the use of Geon 8857 White 126 for any potable water applications.

Bob Hinderer

cc: Woody Ban

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