

AN 4782
deleted

July 8, 1991

VIA FAX

Jim Gray:

Subject: Geon 87241 FDA Clearance

This letter is in regard to your question regarding the use of Geon 87241 in a housewares application.

Those food contact articles used in the household, food service establishments and food dispensing equipment are exempt from FDA Regulatory compliance. I am enclosing a copy of a March, 1983 letter from FDA concerning the so-called "Housewares Exemption." FDA has taken no further action on this issue and is unlikely to do so. However, even though they may be excluded from regulatory control, such items must not adulterate food within the meaning of Section 402 of the FD&C Act.

Based on my review of the formulation of Geon 87241 in light of the intended use in refrigeration control housing under the Housewares Exemption, it is my opinion that this compound would be acceptable for use under these intended conditions. All of the ingredients in Geon 87241 are acceptable for use in food contact applications and are listed on a regulation in 21CFR Parts 172 through 182 or are prior sanctioned for use in food contact applications. However, you should note that we are waiting for the letter of confirmation of the FDA acceptability from one of our raw material suppliers.

Any other use of this compound in contact with food must be evaluated based on the intended use.

R. K. Hinderer

Robert K. Hinderer

Attachment

22477001

BFG21021



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

March 11, 1983

MAR 17 1983

Mr. Wellman C. Bachtel
Toxicologist
The BF Goodrich Company
500 South Main Street
Akron, OH 44318

re: Current status of houseware
exemption

Dear Mr. Bachtel:

This is in regard to your request of January 5, 1983 for the current status of the "Houseware Exemption".

In 1974 FDA concluded that the "Houseware Exemption" was not an accurate statement of the scope of the Food Additives Amendment. Accordingly, we proposed to change the agency's longstanding interpretation to the contrary. The proposal explains that it was the intent of the Food Additives Amendment to include in its scope any potentially migratory substances in food-contact articles intended for use in the household, food service establishments, or food dispensing equipment, and that such items currently on the market must be brought into compliance if not already in conformity with the law.

Final action has not yet been taken on the 1974 proposal, and housewares remain exempt from the food additive provisions of the Act. However, housewares are not exempt from the Act's general safety provisions that apply to the adulteration of food. Anyone manufacturing food-contact articles for use in the household or food service establishments should make sure that nothing from the article imparts flavor, color, odor, toxicity, or other undesirable characteristics to food, thereby rendering the food adulterated within the meaning of section 402 of the FD&C Act.

22477002

BFG21022

Mr. Wellman C. Bachtel Page - 2 -

If you have further questions on this subject, please do not hesitate to contact us.

Sincerely yours,

Marvin D. Mack.

Marvin D. Mack, J.D.
Petitions Control Branch, HFF-334
Division of Food and Color Additives
Bureau of Foods

22477003

BFG21023